UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	*	Master file No. 2:12-MD-02327 MDL NO. 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

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THIS DOCUMENT RELATES TO PLAINTIFFS:

Toni Hernandez
2:12-cv-02073

Karen Doucette
2:12-cv-02125

Sheryl & Kevin E. Lary
2:12-cv-02136

Teresa Scott
2:12-cv-02100

DEPOSITION OF PETER L. ROSENBLATT, M.D.

GYNEMESH PS

COURTYARD BY MARRIOTT
777 Memorial Drive
Cambridge, Massachusetts
July 1, 2016 9:00 a.m.

Maryellen Coughlin, RPR/CRR

EXHIBIT D

APPEARANCES:

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I N D E X

EXHIBITS

EXHIBITS CONTINUED

EXHIBITS CONTINUED

P R O C E E D I N G S

PETER L. ROSENBLATT, M.D.,
having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. CRAWFORD:

Q. Good morning, Doctor. My name is Jeff Crawford, and I'm here this morning to ask you some questions about the opinions you have rendered in this case.

Do you understand that?

A. Yes.

Q. Would you state your full name for the record, please?

A. Peter Rosenblatt.

Q. How would you describe your role in this case?

A. I am -- I was asked by counsel to render my opinion about various aspects of mesh in the cases that were involved here.

(Whereupon, Deposition Exhibit 1, General Prolene, Gynemesh PS and Prolift Expert report of Peter Rosenblatt, M.D., was marked for identification.)

BY MR. CRAWFORD:

Q. Okay. Do you recognize the document that's been marked as Exhibit No. 1?

A. So this a little bit different format than when I presented it, but it looks like this is my general report.

Q. What do you mean a different format than when you presented it?

A. I think when I --

MR. ROSENBLATT: I'll just represent we added the cover page with the case style to it.

A. Yeah. And, actually, when I sent it, I think it was maybe a different font or different size font, but this is my report.

Q. So originally you drafted an expert report, a general causation expert report, and you submitted it to someone?

A. I -- right, I did a report, and I sent it in a Word format. I think maybe like the reason that I took a minute is because I'm not

sure it was doubled spaced the way it is. So it just looked a little bit different than when I sent it in, but this is the report.

Q. Who did you send it to?

A. I sent it to counsel.

Q. What counsel?

A. Mr. Rosenblatt.

Q. And Mr. Rosenblatt's with what firm?

A. With Butler Snow.

Q. Representing Ethicon?

A. Representing Ethicon.

MR. ROSENBLATT: And, Jeff, I'll state on the record, I don't know if you're going to ask, there's no familial connection.

MR. CRAWFORD: That's interesting to know.

Where's the original that you submitted to defense counsel?

MR. ROSENBLATT: And I will just object that under Rule 26 drafts are not discoverable.

THE WITNESS: Can I answer or?

MR. ROSENBLATT: I mean, if it's on your computer, you can say it's on your computer.

A. It's on my computer.

Q. The one that's in front of you right now as Exhibit No. 1, have you ever seen it in that form, specifically in that font and format?

A. Yes, I have. Just different than the Word format that I sent. But I just -- when you asked me, I wanted to make sure that this was my report, and I've gone through it, and this is my report.

Q. Does that document, Exhibit No. 1, contain all the opinions that you hold in this case?

A. You know, I'm happy to answer any questions that you have if there are additional, but I tried to put into the report all my opinions, but if there are others that you want to ask about today, I'm happy to answer that.

Q. Sure. But when you drafted Exhibit No. 1, it was your intention to include in that document all the opinions that you hold in this case?

A. Yeah, I did the best I could with respect to that.

Q. Since you've written it, between

that time and today, are there any opinions that you've -- that you've come up with that aren't in that report?

A. Not that I can think of.

Q. When were you retained by Ethicon?

A. I was not retained by Ethicon. I have had no discussions with Ethicon. I was asked by Attorney Rosenblatt and his firm to review the materials I think back maybe in March or April of this year.

Q. Approximately March or April of 2016 is when you were first approached or contacted by an attorney with Butler Snow about becoming involved in this case?

A. Yeah, if I remember correctly, I think that actually Attorney Rosenblatt contacted me sometime in 2015, but then nothing happened at that point, and it was only when I was contacted earlier this year when, you know, I started to review materials.

Q. When did you start to review materials?

A. I think it was about March or April.

Q. Had you ever done any work for or

work with or for Butler Snow prior to being contacted in regards to this Ethicon case?

A. No.

Q. We are here today to talk to you about your general causation report, right?

A. Yes.

Q. To be clear, you have generated a general causation report about mesh in general, and then you've also been retained as an expert witness on specific cases; is that fair?

A. Yes.

Q. How many specific cases are you also retained for?

A. I believe it was -- I believe it was five cases.

Q. Do you know the names of them off the top of your head?

A. Yeah, I remember there's Hernandez, Lary, L-A-R-Y, Loomis. I can't think of the others right now.

Q. Are those approximately --

A. Ah, Doucette is another one, D-O-U-C-E-T-T-E. Yeah.

Q. Okay.

A. And I think there's one more.

Q. Are those approximately five cases that you're involved in now the only Ethicon transvaginal mesh cases you've ever been involved with?

A. In terms of reviewing for the purposes of --

Q. Yes, sir.

A. -- this litigation.

Q. Yes, sir.

A. Yes. No, I think there was actually one other. One other, and I don't remember the name of that one, but apparently, that's for some reason not going forward.

Q. There's a difference between reviewing cases and writing reports on cases, correct?

A. I suppose so, but I don't know what the difference is.

Q. Well, some of them you review and send back and then others you review and actually write a report and submit a report on, right?

MR. ROSENBLATT: Object to form.

A. So of the four or five, whatever it was that were sent to me, I reviewed the cases and wrote reports on each of the ones that I was

asked to report on.

Q. Okay. Have you been -- have any of the cases been submitted to you by Butler Snow that you didn't write reports on?

A. There was -- you know, I was sent, and actually, it's probably in these boxes. There was I think one other that was sent to me but within a day I received a message that one of the cases I did not need to even look at, so I never actually, you know, looked at that case.

Q. And who did that message come from?

A. Someone at Butler Snow. I don't know if it was Attorney Rosenblatt or someone that he works with.

MR. ROSENBLATT: And, Jeff, I will represent, if I remember correctly, I think it was a case that was either dismissed or -- it went away.

Q. What did you do specifically to prepare for this general causation deposition?

A. In addition to reviewing the records that were sent to me and writing the report and, you know, reviewing some of the literature, re-reviewing some of the literature, and reading through some of the other records

that I had in terms of the IFUs and some internal e-mails within Ethicon, that's general -- and discussions with Attorney Rosenblatt.

Q. I'm particularly interested in the literature that you re-reviewed just prior to coming to your deposition.

Can you identify that literature for me, please?

MR. ROSENBLATT: Object to form.

A. I would have a tough time mentioning which ones because I just -- you know, my mind doesn't work that way. But I looked at some of the RCTs for both, you know, Prolift and Gynemesh, and I re-reviewed the, you know, Cochrane review and systematic reviews.

Q. Do you know what systematic reviews?

A. The one I remember was the SGS systematic review from several years ago.

Q. So as I understand it, as a general causation expert in this case, you've reviewed a lot of literature, fair to say?

A. Well, right. I mean, I've reviewed it in connection with this, but I've also -- I've known this literature from when it was published.

Q. Right. And of all of the literature that you've reviewed over the years concerning transvaginal mesh, you chose to review three particular pieces of literature in preparation for this deposition; is that fair?

MR. ROSENBLATT: Object to form. Mischaracterizes the testimony.

A. Right, what I felt was most important was to review what I thought was the most important Level I evidence.

Q. And what is in your opinion the most important Level I evidence in this case?

A. Well, that would be -- you know, the Level I evidence was what I just mentioned, systematic reviews, the Cochrane meta-analysis and RCTs.

Q. Is there a group of evidence that you categorize yourself as Level II evidence in this case?

A. Yes.

Q. What is Level II evidence? What is the Level II evidence comprised of?

A. I wouldn't be able to name it off the top of my head but, you know, non-randomized studies, so prospective cohort studies and some

large retrospective studies.

Q. Is there a Category III? Is there a Level III category of evidence in your mind?

A. Yes.

Q. What does that consist of?

A. You know, either, either case reports or opinions, expert opinions.

Q. Would that include the expert opinion of Dr. Rosenzweig?

A. Well, I've read -- I've read Dr. Rosenzweig's -- I'm trying to remember what I've read from him. I know I've read an expert report in connection with this case, you know, one of the cases, and I don't remember if I read anything in the medical literature from Rosenzweig specifically in connection with the mesh literature.

(Whereupon, Deposition Exhibit 2, Rule 26 Expert Report of Bruce Rosenzweig, M.D., was marked for identification.)

BY MR. CRAWFORD:

Q. I'm going to hand you what's marked as Exhibit No. 2 to your deposition. Do you recognize that document?

A. Yes.
Q. What is that?
A. This is Dr. Rosenzweig's expert report.
Q. Is that his general causation report?
MR. ROSENBLATT: For TVT?
A. Can you show me where this says exactly what it is about? I'm happy to read it all, if you want.
Q. If you'll just peruse it briefly and tell me how you would describe that report. It doesn't appear to be specific to any one particular case, does it?
A. It does not. It appears to be about TVT.
Q. Did you review Exhibit No. 2 in preparation for this deposition?
A. I remember seeing a report by Rosenzweig. I assume that this is it. I can't say for certain, but I did see -- and if this is the one that I reviewed, then I did. I didn't review it specifically for this deposition, but I've read through a lot of reports in the last three months, and I believe this is one of them.

Q. When was the first last time that you reviewed a Rosenzweig report?

A. It's got to be over a month ago. Probably more like two months ago.

Q. There's reference to literature in his report, correct?

A. There appears to be, yes.

Q. When you reviewed Dr. Rosenzweig's report, did you pull any of the literature that's cited or referenced in that report?

A. Can you tell me which ones you're referring to?

Q. Any of it.

A. Oh.

Q. For example, do you recall when reviewing Dr. Rosenzweig's report reading any footnotes or anything contained in that report and looking up the literature that's referenced therein?

MR. ROSENBLATT: And I'll just represent he was not retained to offer opinions on TVT.

A. So I don't recall specifically, but I'm happy -- you know, if there is a reference you want me to tell you -- you know, if you want

to point to a reference, then I'll be happy to tell you if I read that. But did I go through his reference list and look all these articles up, no.

Q. Yes, sir, that's what I was asking.

A. No, I couldn't do that. Time did not permit it.

Q. Do you recall looking any of them up?

A. No, I guess what I'm saying is that there are -- oh, here we go. It's here at the bottom.

MR. ROSENBLATT: I think it's mostly company testimony, but he might have --

THE WITNESS: That's what it looks like.

MR. ROSENBLATT: -- a couple literature references in there.

A. So that is correct. So I have no idea about these company references. Like, for instance, Reference 246 is an article from de Tayrac in 2004, you know, that I've seen. And there is another reference -- it actually doesn't have a number by Jacquetin that I have seen, and some of these reference videos which I have not

seen.

Q. Are there types of evidence that you consider Level IV evidence?

A. If you could tell me what Level IV is. I don't recall.

Q. I don't know. I was asking you. Do you know --

A. I can't remember if there is a Level IV evidence. Yeah, for example, No. 11, Clavé, I've read through that as well.

Q. In addition to what you've identified as Level I, Level II and Level III evidence, you've also reviewed internal e-mails in preparation for this deposition, correct?

A. Well, I have read through them but, you know, not specifically for this, in preparation for this. I read them before I wrote my report. Probably the last time I read through internal documents was maybe, you know, four weeks ago.

Q. Do any particular internal e-mails that you reviewed approximately four weeks ago come to mind?

A. Not specifically.

Q. There's an attorney sitting to your

left, correct?

A. Yes.

Q. He's from Butler Snow?

A. Yes.

Q. Did you have an opportunity to meet with him prior to this deposition?

A. I did.

Q. Where did that meeting take place?

A. We met for the last hour and a half, two hours in the hotel.

Q. Your deposition is being taken in a hotel?

A. Yes.

Q. In Cambridge, Massachusetts?

A. Yes.

Q. And for approximately an hour and a half or so you were able to meet with defense counsel prior to walking into this conference room?

A. Correct.

Q. Did you take any notes during that meeting?

A. No.

(Whereupon, Deposition Exhibit 3, Notice to Take Deposition of Dr. Peter Rosenblatt, was marked for identification.)

BY MR. CRAWFORD:

Q. No. 3 is a deposition notice for today's deposition. Do you recognize that?

A. I do.

Q. Have you looked at Exhibit A to that deposition notice or I should say Schedule A?

A. Yes, I have.

Q. Schedule A is a list of documents and tangible items that you were requested to bring with you to your deposition today; is that true?

A. Do you know -- can you take a look at this, 'cause I don't think -- it's missing some pages. I don't think it actually says Schedule A anywhere.

MR. ROSENBLATT: The version I have cuts off at page 7.

THE WITNESS: Oh, is it on the back pages maybe.

MR. ROSENBLATT: I think you maybe

tried to print double-sided but it --

Q. That one's double-sided.

A. Okay. What was the question again?

Q. Did you have an opportunity to review Schedule A?

A. I have, yes.

Q. And have you brought documents and tangible items with you today that are responsive to Schedule A?

MR. ROSENBLATT: And I'll just note for the record that I think we filed objections but if we haven't, they will be filed, but you can answer.

A. Right. So that was one of the reasons we met earlier, is that Attorney Rosenblatt brought things that I had provided to him, and so we went over those, which are sitting in front of me.

Q. Okay.

A. It's all yours (indicating).

Q. There's a large number of, in my opinion, a large number of -- several folders containing documents sitting in front of me here at this conference table.

Can you make an effort to summarize

what's contained here?

A. Sure. So first are my billing records for work done in these cases.

Q. Okay. I'm going to mark that as Exhibit No. 4. Bear with me just a second.

A. Yeah.

Q. Actually, it appears to be two different documents; is that right?

A. Correct.

Q. Okay. I will mark the first one as Exhibit No. 4 and the second as Exhibit No. 5.

(Whereupon, Deposition Exhibit 4, Invoice #2, was marked for identification.)

(Whereupon, Deposition Exhibit 5, Invoice #1, was marked for identification.)

BY MR. CRAWFORD:

Q. And, again, for purposes of the record, Exhibits 4 and 5 are documents that relate to the work you've done on these files or on this case and the amount charged, correct?

A. Correct.

Q. While we have them out in front of us, there appears to be one invoice, specifically

Invoice No. 1. It's dated June 12th, 2016. That's Exhibit No. 5; is that right?

A. Yes.

Q. And that invoice is for a total of $63,200.

A. Correct.

Q. Then there's a second invoice that's marked as Exhibit No. 4, and that invoice is dated --

A. Somehow that did not get translated properly.

Q. So the invoice marked as Exhibit No. 4 doesn't have a date. However, it does have a --

A. It was sometime after this date (indicating).

Q. The invoice marked as Exhibit No. 4 doesn't have a date at the top, but you believe that that invoice was generated at sometime after June 11th, 2016?

A. Probably after June 12th.

Q. Okay. And the amount for that invoice is $21,200?

A. Correct.

Q. So to date, you've billed

approximately $84,400 for your services as an expert witness in this case?

A. Correct.

Q. Does that include your time as a general causation expert only or is that also charges for the work you've done as a case-specific expert?

A. Both.

Q. Okay, let's turn to the next document or set of documents that you brought in response to Schedule A to your deposition notice.

A. Well, there are a number of folders where there are PowerPoint presentations that have been printed out, and the first set is labeled TVT-O. The second set is labeled TVT-S. The third group is referred to as additional slides. The next are presentations labeled TVT Exact. The next are presentations labeled TVT. The next are presentations, yup, labeled Prosima™. And the next are a group of presentations labeled Ethicon.

MR. ROSENBLATT: Jeff, I'll just represent there are two copies of each presentation or there should be two copies of each presentation in there.

THE WITNESS: My phone is on vibrate, but I may be getting a text just 'cause one of my partners has a patient who has a significant problem, and I may get a text about it, and I'll try not to let this interfere with the deposition, but I just want to let you know I'm not being rude if I check a text.

Q. Of course. I completely understand.

I ran into one I got confused on. Let's go off the record?

(Discussion off the record.)

(Whereupon, Deposition Exhibit 6, Presentations, was marked for identification.)

BY MR. CRAWFORD:

Q. Doctor, we've finagled with some exhibits and documents. I'm holding in my hand Exhibit No. 6 to your deposition, correct?

A. Okay.

Q. What is this?

A. These are presentations that I've given in the past that are related to the topics that we're discussing.

Q. And are the documents contained in

Exhibit No. 6 documents and things that you've reviewed just prior to coming to your deposition in preparation for this deposition?

A. I honestly just scanned through those to make sure those were the ones that I had sent. But have I read all the slides, absolutely not.

Q. Of all the documents, the things that you've reviewed in conjunction with being an expert on transvaginal mesh, is there any particular reason you chose these documents marked as Exhibit No. 6 to refresh yourself on and look at just prior to your deposition?

A. They were not to refresh my memory. They were just in response to Schedule A I guess it is. Yeah, Schedule A. Any presentations that had to do with the topics that we're discussing.

Q. Returning to -- our attention to Schedule A of your deposition notice, did you bring with you a current copy of your curriculum vitae?

MR. ROSENBLATT: And I'll just represent I think the current version was attached as an exhibit to his general deposition.

Q. Is that true, Doctor?

A. Yes, it is.

Q. No. 2 of Schedule A requires you or requests you to bring with you any and all documents in your possession including but not limited to correspondence, notes, videos, CVs, DVDs, flash or USB drives, photographs, databases or materials in other form provided to you or created by you which you relate to your opinions, expected testimony or development of your opinions in this litigation.

Have you brought those with you today?

A. Anything that I thought was relevant that I brought that I knew was accessible.

Q. Is that contained in Exhibit No. 6 or are there other documents that are responsive to that particular request that aren't contained in Exhibit No. 6?

MR. ROSENBLATT: And, Jeff, I will just again note for the record we have filed objections to the notice and Schedule A.

MR. CRAWFORD: I understand.

A. Anything I thought that was relevant that I could get my hands on are there.

You know, what comes to mind, for instance, is there may be like marketing DVDs that I received 15 years ago that I have no idea where they exist. So I made the best effort I could to bring what, you know, was asked of me.

Q. Very good. Referring to No. 5, have you reviewed any deposition testimony in preparation for this deposition today?

A. I've seen some depositions from other experts that I have scanned through that I've tried to read, and I briefly looked through a deposition that I did for a Bard litigation which was I think about two years ago.

Q. How long ago did you review the deposition testimony of other experts?

A. It's varied over a number of weeks. Well, I did look at one within the last two or three days as well.

Q. Which one was that?

A. There was one -- I'm going to say his name wrong. Sepulveda.

Q. Okay.

A. And Tomezsko. And there may have been one other. Toglia.

Q. Are those the only deposition

transcripts you can think of right now?

A. Off the top of my head, yes.

Q. Schedule A requests you to bring with you those deposition transcripts. Did you do that?

MR. ROSENBLATT: I'm just going to object, Jeff. No, he didn't bring them with him.

Q. Did you review any pleadings in connection with preparing for this deposition?

A. I guess I'm not familiar with that term exactly. I've heard the term, but I don't know if I've seen pleadings.

Q. Have you seen anything that you think looks like it has been filed with the court?

A. Not that I recall.

Q. You haven't brought any pleadings with you today, have you?

A. I guess not.

Q. If you don't know what they are, you haven't brought them then.

Do you have any photographs of any of the case-specific plaintiffs that you're involved in?

A. I don't recall if any photographs

were sent to me about those specific cases.

Q. Do you know off the top of your head whether you've seen a photograph of Toni Hernandez?

A. I would be happy to look at anything and tell you if I have seen it. I just don't remember off the top of my head.

Q. As you sit here right now, you don't recall ever seeing a photograph of Toni Hernandez?

A. I may have, but I don't want to state that I did or didn't. I just don't remember. But I'd be happy to look at a photograph and -- if you showed me a photograph, I would definitely be able to tell if I saw it before.

Q. The invoices marked as Exhibits No. 4 and No. 5 to your deposition, do those include any time sheets, invoices, time records or billing records that record or document the work you've performed in this case?

A. I'm not sure I --

MR. ROSENBLATT: Object to form.

A. Yeah. I'm not sure I understand. Sorry. I'm not sure I understand the question.

Q. Do you have any other time sheets or any other documents that reflect the specific work you've done on this case, other than the invoices that are marked as Exhibits No. 4 and No. 5?

A. No. Everything I've done, that's how I record it, and then I generate an invoice based on that.

Q. Are there other documents other than 4 and 5 that contain information that was used to generate Exhibits No. 4 and 5?

A. No.

Q. Do you prepare these invoices yourself?

A. I do.

Q. Using what software?

A. Word. I don't mean that like when my son says word. I mean "Word."

Q. I noticed you didn't flash any gang signs when you said that, so.

A. I felt funny when I said that. Microsoft Word.

Q. There we go. The point is you don't generate time sheets and then hand them to someone who then uses that information to compile

or generate these invoices?

A. No.

Q. Something tells me you didn't bring with you copies of your Schedule C and Form 1099 of your tax records for the preceding five years.

MR. ROSENBLATT: You don't need to answer that. No, we're not producing that.

Q. No. 14 requests that you produce all documents related to your involvement with Ethicon's professional education, including, but not limited to any and all PowerPoints, course materials, outlines, videos or presentations, live surgical presentations, marketing evaluations created by or provided to you related to any pelvic mesh product sold by Ethicon.

Do you have any materials or items that fit that description other than what you have already produced and has been marked as Exhibit No. 6 to your deposition?

A. The only thing I could think of besides what's already been produced is I did -- I did personally create a video that was used by Ethicon for tensioning slings, and we can make that available. It's a short video on how to tension a sling.

Q. When was that video created?
A. Oh, it's got to be ten years ago.
Q. Where is it right now?
A. It's -- where's the video?
Q. Yes, sir.
A. I mean, they made it into DVDs, and I most likely have a copy of the video on my computer.
Q. Yes, sir, I would appreciate it if you'd produce that.
Are we in agreement on that?
MR. ROSENBLATT: If he's able to find it and send it to me, I'll pass it along to you.
Q. Is there any particular reason you didn't bring that with you today?
A. No. I'm happy to provide it, though.
Q. Do there exist any transcripts or statements between you and any governmental agency regarding any pelvic mesh product used for treatment of stress urinary incontinence or pelvic organ prolapse?
A. I don't believe so.
Q. No. 18 requests that you produce or

bring with you any and all documents relating to any presentations, PowerPoints or lectures regarding any female pelvic mesh product used for treatment of stress urinary incontinence or pelvic organ prolapse.

Have you brought those with you?

MR. ROSENBLATT: And I'll just note our objection to being overbroad and vague.

A. Well, I was going to ask you, are you talking about Ethicon products there?

Q. The request specifically says any female pelvic mesh product used for treatment of stress urinary incontinence or pelvic organ prolapse.

A. So I know that there are other presentations. I did not bring them. And with permission from counsel, I would be perfectly willing to provide those to you.

Q. As you sit here today, what presentations are you aware of that you're in possession of that weren't brought with you today?

A. Well, what comes to mind is that I in the last several years have been doing some teaching for Boston Scientific as well as some,

you know, presentations that I've done on my own not in connection with Boston Scientific that have included the Uphold mesh device and before that Pinnacle.

I think when I read this -- I'm only now seeing that it was just any treatment, and I was thinking about Ethicon and that's why I produced those.

Q. If it had said Ethicon specifically, have you satisfied that requirement as set forth in No. 18?

A. Yes.

Q. We're through with the notice. Do you want to take a break?

(A break was taken.)

BY MR. CRAWFORD:

Q. Doctor, is it fair to say that the risks of you using mesh in pelvic reconstructive surgery are well-known?

A. Yes.

Q. And they've been well-known for a long time?

A. Right, decades.

Q. Some risks are common with pelvic reconstructive surgery regardless of whether mesh

is used?

A. Correct.

Q. Such as bleeding, infection, injury to adjacent organs, scarring and dyspareunia?

A. Correct.

Q. Then there's some risks that are unique to surgeries that involve the use of mesh, including mesh erosion into the surrounding organs?

A. So when you put it that way, you know, erosion into surrounding organs can happen with any permanent material like suture. But when you say, quote/unquote, mesh erosion, you can't get -- you can't get erosion of mesh unless you use mesh. But we certainly see erosions of permanent sutures, for instance, into surrounding organs or into the vagina.

Q. I understand that. I appreciate that clarification.

But mesh erosion is unique to surgeries that involve the use of synthetic mesh?

A. Correct.

Q. Mesh erosion into surrounding organs such as the bladder and the urethra and the rectum are a known risk associated with

Prolene® mesh, fair?

A. Well, no. When you say Prolene® mesh -- Prolene® mesh is a trade name, right --

Q. Sure.

A. -- so it can happen with any polypropylene mesh. Fortunately mesh erosion into a surrounding organ is exceedingly rare as opposed to mesh exposures.

Q. But it is a known risk. Whether it's rare or not it's a known risk?

A. It is a known risk.

Q. And for clarification, Prolene® mesh is a synthetic polypropylene mesh?

A. It's one of the -- it's one type of polypropylene mesh.

Q. And in October of 2008, the FDA issued a pelvic health notification regarding transvaginal mesh.

A. Correct.

Q. That would include Ethicon's Prolene® mesh, right?

A. Correct.

Q. The FDA stated that surgeons and patients should be aware of what's termed "serious complications" associated with surgical

mesh placed through the vagina, including mesh erosion and exposure?

MR. ROSENBLATT: And, Jeff, do you have a copy to show him or do you plan on marking that as an exhibit?

MR. CRAWFORD: I don't. I'm making reference to it as it was described in his report.

A. Just one second.

(Discussion off the record.)

A. I'm sorry, did you say that we did have a copy of the 2008 FDA Public Health Notification?

MR. ROSENBLATT: I think he said he was just referring to your report.

A. Okay, got it.

Q. You're pretty familiar with that --

A. Yes, I am.

Q. -- aren't you?

A. Yeah, I just wanted to know if Paul wanted to have it in front of me, but yes, I am.

Q. I'll re-ask the question.

A. Thank you.

Q. The FDA stated that surgeons and patients should be aware of what it termed

"serious complications" associated with surgical mesh placed through the vagina including mesh erosion and exposure; is that right?

A. That's correct.

Q. And that would include Ethicon's Prolene® mesh as indicated?

A. Yes.

Q. In 2008, did the FDA warn the public that over the previous three years it received over 1,000 reports of complications that were associated with surgical mesh devices used to repair pelvic organ prolapse and stress urinary incontinence?

A. That is correct.

Q. And those devices also included those made with Ethicon Prolene® mesh, true?

A. That is correct.

Q. Was it noted by the FDA that the most frequent complications include exposure of the mesh through the vagina -- through the vaginal epithelium, infection, pain, urinary problems and recurrence of either prolapse or incontinence?

A. Well, if I remember correctly, the most common was the mesh exposure, but those

others that you mentioned are also potential risks but not necessarily related specifically to mesh, but with any -- you know, infection can happen, scarring can happen with any pelvic surgery.

Q. Did the FDA in 2008 stress the need for adequate informed consent and specialized training for specific mesh kits?

A. Yes, they did.

Q. And did the FDA also stress the need to be vigilant for mesh complications including erosion and infection as well as complications associated with the tools used in the placement of transvaginal mesh?

A. Yes, they did.

Q. In 2008 did the FDA also recommend that surgeons inform their patients that the implantation of surgical mesh is to be considered permanent and that some complications associated with the mesh may require additional surgery?

A. Yes, they did.

MR. ROSENBLATT: It's on page 13 and 14.

THE WITNESS: Thank you.

Q. Finally, did the FDA in 2008 also

encourage surgeons to inform their patients about potentially serious complications affecting their quality of life including pain during intercourse and vaginal scarring?

A. Yes, they did.

Q. In 2011, the FDA issued an update of that 2008 notification based on a continuing analysis of adverse events that had been reported to the FDA between 2008 and 2011.

A. Correct.

Q. While basically reiterating the information from the 2008 public health notice, the FDA went further in 2011 stating that the complications noted in the 2008 notice were not rare?

A. That's what they reported, correct.

Q. In fact, from January 1st, 2008, through December 31st, 2010, the FDA had received 2,874 additional reports of complications associated with surgical mesh devices used to treat pelvic organ prolapse and stress urinary incontinence?

A. Correct.

Q. Those devices would include the devices made with Ethicon Prolene® mesh?

A. Presumably, yes.
Q. Do you think that it was wrong for the FDA to have told the public that complications associated with transvaginal mesh are not rare?
A. I think it was wrong of the FDA.
Q. Why?
A. As stated in my report, there were, you know, 1503 reports to the FDA about complications associated with mesh, and in the -- in I believe it's the white paper that was associated with the safety update, they talk about that there were approximately 75,000 transvaginal mesh cases done in the United States per year. And if you do the math, over that three-year period, that's over 200,000 cases, and you've got 1503 reports. So if you do the math, it comes down to .06 percent which in my mind -- if a doctor was operating on me and said your chance of a serious complication was about a half a percent, I would consider that pretty rare, personally.
Q. Do you criticize the FDA for opening the door to plaintiffs attorneys who've now filed tens of thousands of cases against

medical device manufacturers for transvaginal mesh?

A. I think that's part of the situation. I don't think it rests solely with the FDA, but I think that contributed to it.

Q. What else do you believe contributes to it?

MR. ROSENBLATT: Object to form.

A. I believe the fear mongering with all the plaintiff ads on TV have done a real disservice to women throughout this country.

Q. Anything else?

A. The only thing that comes to mind are, you know, I recall seeing an article in Reuters about medical lenders who are also taking advantage of, I believe, the situation and taking advantage of women who may have problems with mesh.

Q. In what ways are they taking advantage?

A. By lending patients money and jacking up the bills artificially so that when women get their settlements most of the settlement money goes to the entrepreneurs and not to the patients who have been hurt by these,

potentially hurt by these procedures.

Q. What evidence do you have that that's going on?

A. Just an article that I read in Reuters about this.

Q. Do you have any personal knowledge regarding that going on?

A. Yes, my personal knowledge is my discussions with a urogynecologist colleague of mine named Dr. Cassidenti in the Los Angeles area who was contacted by one of these medical lenders and was asked to remove mesh in women and would be paid cash to do this.

Q. Any other evidence?

A. Not that I can think of.

Q. Have you yourself been approached by any such lenders?

A. I have not.

Q. You perform around 300 surgeries for prolapse and incontinence every year?

A. Roughly.

Q. Approximately how many of those 300 surgeries that you perform each year involve the use of Ethicon Prolene® mesh?

MR. ROSENBLATT: Object to form.

Jeff, are you referring specifically to Prolene® or are you using Prolene® more broadly? Just --

MR. CRAWFORD: I want to know Prolene®, how often does he use Ethicon's Prolene® mesh. And my next question will be in how many of those procedures do you use synthetic mesh that's not Ethicon Prolene® mesh?

MR. ROSENBLATT: Jeff, I'm not trying to be difficult but Gynemesh® PS is also made from Prolene. So I'm just wondering are you asking about Prolene® or Prolene in general.

Q. Prolene in general.

A. So it varies per year, but if you want to know currently --

Q. Yes, sir.

A. So I'm still using TVT-O, and occasionally Gynemesh®. I think those are the only two products that I'm currently using.

Q. Were you using those last year?

A. Yes.

Q. And last year you performed approximately 300 surgeries?

A. Correct, but that wasn't the -- that wasn't the only sling type that I was using.

Q. And that's what I'm getting at.

What percentage of your surgeries last year involved Ethicon mesh, those two products that you just referred to?

A. I would say of the -- I probably do roughly 100 sling operations a year, maybe 100 to 125, and percentage-wise, probably 40 percent of them are TVT-O, but that's been decreasing over the last couple years. So maybe this year it's probably more like 30 percent or 25 percent.

Q. So last year approximately 40 percent of your 100 sling operations involved the use of Ethicon products?

A. I believe that's correct.

Q. And that number has decreased this year?

A. Correct.

Q. Why?

A. Only because I'm using more of a different transobturator sling. I still do a lot of transobturator slings, but I'm using more of the Boston Scientific slings at this point.

Q. Why did you switch?

A. Well, I haven't switched, but my fear is that over the past --

Q. And I'm sorry to cut you off. Let

me rephrase the question so you don't have to answer twice.

A. Sure.

Q. Why have you -- I don't mean to be rude. I'm just trying to save you the time.

A. Are you talking to me?

Q. Yeah.

A. Okay.

Q. What is the reason that you've decreased your use of Ethicon products and increased your use of Boston Scientific products?

A. Right. So if I thought that I could use the Ethicon products from now until the day I retire, I would, but over the last couple years, Ethicon has dropped their sales force, and there are rumors that they may stop manufacturing altogether. So I wanted to get prepared for that day, and so I started looking at other sling products from companies that I believe will continue to be around for the long term, and that's why I have transitioned myself slowly to Boston Scientific.

Q. When did you begin that transition?

A. I would say not long after they dropped their sales force.

Q. When was that?
A. I don't remember precisely, but I'm going to say about three years ago.
Q. Approximately 2013?
A. I believe so.
Q. In 2013, were you still performing approximately 100 sling procedures?
A. 100 to 125, yeah.
Q. Back then what percentage of your sling procedures involved the use of Ethicon mesh?
A. I believe it was 100 percent.
Q. And today, three years later, that's down to approximately 30 percent?
A. Correct.
Q. What's the BSC product that's comparable to the Ethicon product you're replacing it with?
A. Yeah, it's not really comparable, but it's an outside-in as opposed to the inside-out transobturator sling, and it's called the Obtryx II. Roman numeral II, O-B-T-R-Y-X.
Q. Back to the FDA. In conjunction with its 2011 update, did the FDA conduct a systematic review of the published scientific

literature to evaluate the safety and efficacy of transvaginal mesh for pelvic organ prolapse?

A. Yes.

Q. Did that systematic review demonstrate that transvaginal mesh repairs do not improve symptomatic results or qualify -- strike it.

Did that systematic review demonstrate that transvaginal mesh repairs do not improve symptomatic results or quality of life over traditional non-mesh repair?

MR. ROSENBLATT: Object to form.

A. That's what they stated.

Q. Did the literature review conducted by the FDA reveal that mesh used in transvaginal repairs introduces risks not present in non-mesh surgery for pelvic organ prolapse?

A. That is what the FDA said.

Q. Did the FDA discover in 2011 that there was no evidence that transvaginal repair to support the top of the vagina or the back wall of the vagina with mesh provided any added benefits compared with traditional surgery that did not use mesh?

A. That is what the FDA stated.

Q. Is it fair to say that you recommend for the use of transvaginal mesh -- strike that.

Is it fair to say you recommend the use of transvaginal mesh in pelvic reconstructive surgery?

A. Not as a general statement, but in select cases, I do.

Q. You're not suggesting that mesh is recommended for all patients who are in need of surgical repair?

A. Absolutely not.

Q. There are alternatives to using synthetic mesh in pelvic reconstructive surgeries?

A. There are.

Q. Sometimes transvaginal mesh is the best option but sometimes an alternative may be the best option?

A. That is correct.

Q. Do you believe the FDA in its public health notices of 2008 and 2011 presented a biased view of transvaginal mesh?

A. Yes.

Q. Why?

A. For the reasons I already stated, that their interpretation of the -- whether or not serious complications were rare is based on their interpretation of the data. And, also, I think the bias is that any return trip to the operating room is considered a serious complication by the FDA but that return to the operating room may be a minor procedure such as excision of a few fibers of mesh that have been exposed in the vagina, and coupled along with that is that if a patient fails a prolapse repair with native tissue and has to go back to the operating room to have a whole another procedure done for her prolapse, that is not considered a serious AE, or adverse event, by the FDA, but it's a much bigger operation. So that, to me, demonstrates an inherent bias in their notifications.

Q. Generally speaking, do you believe that a complication that requires a woman to go to the operating room for surgical repair of that complication is considered a serious complication?

MR. ROSENBLATT: Object to form.

A. So that is how the FDA sets up what

they consider a serious adverse event, is a return trip to the operating room, and I'm not taking that lightly at all. But from a clinical standpoint, I would much rather -- if I had to choose between taking someone back for a small mesh exposure incision under local anesthesia versus an entirely new operation to repair recurrent prolapse with the inherent scarring and... I would much rather, if I had to choose, take the former rather than the latter.

Q. If I were to tell someone the complication Woman A had is a serious complication, and I know it was a serious complication because it required her to go to the emergency room to repair it, do you agree with that statement?

MR. ROSENBLATT: Object to form.

A. I guess I'm not sure what you're talking about in terms of going to the emergency room.

Q. I meant operating room. I'm sorry. I got to re-ask it.

A. Please.

Q. If I were to tell someone Ms. Smith has a serious complication with her transvaginal

mesh, and the reason I know it's a serious complication is because she had to go to the operating room to have it repaired, do you think I'm making a fair statement?

A. I guess what I'm saying is I don't think that's unreasonable. What I'm saying is to consider that a serious complication but not to consider a recurrent prolapse requiring a whole new operation for prolapse, not considering that a serious complications is somewhat hypocritical.

Q. I understand. And I don't mean to belabor the point, but is it fair to say that by it's very def- -- strike it.

Is it fair to say that a complication that requires a woman to go to the operating room for a surgical repair that by its very nature should be considered a serious complication?

MR. ROSENBLATT: Object to form. Asked and answered.

A. I think that that is reasonable, but there are different degrees of serious adverse events. And if the FDA wishes to categorize that as a serious adverse event because it's a return to the operating room, I

don't disagree with that. I'm talking about the hypocrisy about not considering a return trip to the operating room for recurrent prolapse not a serious adverse event, that's all.

Q. Do you have any reason to believe that what you consider to be a misrepresentation of the data by the FDA was intentional on the FDA's part?

MR. ROSENBLATT: Object to form.

A. I have no reason to believe that.

Q. For example, do you believe that the FDA has some kind of a vendetta against synthetic mesh manufacturers?

A. No, I don't believe that is true at all.

Q. Can you imagine any reason why anyone at the FDA would want to mislead the public with a biased view of risks associated with the use of transvaginal mesh to treat women's health issues?

A. I can't think of any reason why they would want to do that.

Q. Two risks unique to transvaginal mesh include mesh exposure through the vaginal wall and also erosion, which is the migration of

the mesh, into other organs. Is that right?

A. Right.

Q. Do you hold the opinion that most cases of mesh exposure are minor complications and are even asymptomatic?

A. That's true much of the time, correct.

Q. On what studies or peer-reviewed medical literature is that opinion based?

A. It's actually based on many studies throughout the literature that many of the mesh exposures are asymptomatic and that many mesh exposures require either just an in-office procedure or just observation or treatment with estrogen cream. And, in addition, that's been my experience for the past, you know, 15 years or so in my clinical practice, that most of the mesh exposures are either asymptomatic or minimally bothersome to a patient.

Q. And by most, you mean the majority?

A. The majority, correct.

Q. Can you identify off the top of your head any particular peer-reviewed literature that supports that opinion?

A. Yes. I'd have to look to

specifically mention names, but a number of the RCTs on Prolift. I believe Hiltunen. I believe Nieminen. I'm probably saying that wrong. Talk about how often mesh exposures are asymptomatic.

Q. Any others off the top of your head?

A. No, but I'd be happy to look at any, and there are many. It's throughout the literature.

MR. ROSENBLATT: Did you want him to go through his expert report and pull out any references for you?

MR. CRAWFORD: No, I don't need that. I just wanted to know what he could think of off the top of his head. Thank you, though.

Do you hold the opinion that there's a significantly higher rate of recurrent prolapse with native tissue repair as compared to use of transvaginal mesh.

A. Yes.

Q. On what studies or peer-reviewed medical literature is that opinion based?

A. On many. I mean, even the RCTs such as Altman and several others that, you know, I'm familiar with but just don't come to mind,

but I've read many, many RCTs as well as -- well, the RCTs, that the rate of recurrent prolapse is much higher with native tissue repairs.

Q. For the benefit of a jury, what is an RCT?

A. Oh, RCT. It's a randomized controlled trial.

Q. Do you agree that there's no chance of mesh erosion or exposure with a native tissue repair?

MR. ROSENBLATT: Object to form.

A. That's true when you use the word mesh, but it's certainly not true with native tissue repairs that use permanent synthetic materials where there's a risk of erosion. And, you know, in fact, just that you mentioned it, the one that leaps off my mind is the Iglesia RCT comparing Prolift to native tissue repair that was stopped during an interim analysis because the mesh exposure rate was over 15 percent, which was a predetermined percentage at which they would stop the procedure, but in the same article, they talk about the native tissue repairs showing a GORE-TEX exposure rate of over 15 percent as well, but they don't -- you know,

they don't talk about cancelling the native tissue repairs because of over 15 percent exposure rate.

Q. You say in your report that the Gynemesh® PS mesh used in Prolift is not defective just because a small percentage of patients may experience exposures or other well-known and acceptable complications.

A. Correct.

Q. In your opinion, what percentage of Prolift patients would have to experience mesh exposures for you to consider the Prolift device defective?

MR. ROSENBLATT: Object to form.

A. So I don't think there's a specific number, and different studies show different exposure rates. So I think a lot of it has to do with technique, surgeon technique, as well as, you know, the factors associated with the patient. You know, clinical factors, like age and estrogenization and menopausal status, obesity, comorbidities like diabetes. But, to me, that does not, a specific percentage does not denote a defect in the product itself.

Q. So there is no particular specific

percentage at which you would say this is a defective product?

MR. ROSENBLATT: Object to form. Asked and answered.

A. No, only in that different studies -- you know, I've seen exposure rates as high as 20 percent. I've seen exposure rates of 5 percent or 2 percent. So, you know, every study is different, and you're going to have different exposure rates.

Q. Your report says the medical literature commonly reports that eight or nine out of ten women who have Prolift report that the Prolift surgery improved their quality of life, correct?

A. Correct.

Q. What medical literature are you referring to or relying upon to make that statement?

A. Can I take a look at --

MR. ROSENBLATT: I think you've got it.

THE WITNESS: Oh, I do?

Q. Page 46. The very first sentence on page 46.

A. Oh, thank you. You know, as an example, the article I quote with Feiner from 2010 shows that despite some patients developing de novo dyspareunia, the overwhelming majority, in this case 94 percent of the women, say they would have had the same surgery again, and over 90 percent would recommend it to a friend.

Q. Is there anything other than the Feiner report in 2010 on which you base your opinion that the medical literature commonly reports that eight or nine out of ten women who have Prolift report that the Prolift surgery improved their quality of life?

A. I believe that there -- there is other literature, and I'm trying to remember. I believe possibly Lowman, L-O-W-M-A-N, discusses that as well. That they specifically looked at dyspareunia rates, but that most women were very satisfied with the procedure, and that even the dyspareunia was considered mild for most women.

Q. Are there any other studies?

A. There are --

MR. ROSENBLATT: Object to form.

A. -- but nothing that comes to mind.

Q. What year was the Lowman study?

A. What year was the Lowman study?
Q. Yes. Do you recall?
A. I don't recall off the top of my head.
Q. Okay.
A. 2008.
Q. Thank you. What's your understanding of Bruce Rosenzweig's role in this case?
MR. ROSENBLATT: Object to form.
A. I know that Dr. Rosenzweig has been identified as an expert for the plaintiff.
Q. Do you know anything beyond just the fact that he is an expert for the plaintiff? Do you know what he is an expert in?
MR. ROSENBLATT: Object to form. Assumes facts not in evidence.
Q. Let me rephrase.
Do you know what subjects Bruce Rosenzweig is held out to be an expert by the plaintiffs' lawyers in this case?
A. Not specifically, although I've read his report and I believe he discusses the specific qualities of mesh, mesh properties.
Q. And do you know his specialty?

A. I believe he's a urogynecologist.
Q. Do you know Dr. Rosenzweig personally?
A. I may have met him many, many years ago.
Q. Do you have any specific recollection of that?
A. Yeah, I remember he taught at a course I attended in the late 1990s. I believe it was actually in Frisco, Colorado. And then he sort of disappeared off the grid for a number of years before he resurfaced.
MR. CRAWFORD: I will respectfully object to the non-responsive portions of that answer.
MR. ROSENBLATT: I think he's referring to his skiing videos.
BY MR. CRAWFORD:
Q. Was there anything -- I mean, no offense, but the late 1990s has been a while.
Is there any particular reason you recall meeting Dr. Rosenzweig at that conference?
A. No, just that I remember him lecturing at a conference I attended out there.
Q. Do you recall what topic or subject

he lectured on?

A. No.

Q. What do you know about Dr. Rosenzweig's reputation in the medical community?

A. Only that he is -- I've seen his name in connection with a number of legal cases as a plaintiff expert. Not just limited to Ethicon but in a number of cases.

Q. Anything else?

A. No.

Q. Do you have any reason to believe Dr. Rosenzweig is a biased witness in this case?

A. I have no knowledge about anything like that.

Q. Dr. Rosenzweig has opined that Ethicon's Prolene® mesh is not suitable as a permanent implant for pelvic reconstructive surgery because the pores are too small. Do you agree with that?

A. No.

Q. Why not?

A. So the Prolene® mesh, you know, has been used in literally, you know, millions of sling cases with phenomenal results.

I mean, if anything, you know, the TVT products have revolutionized the field of urogynecology, and that's not just from my personal experience, which it is, but it's also from, you know, hundreds of peer-reviewed, if not thousands of peer-reviewed, articles about the success of the material.

Q. I understand that you're an advocate of the mesh, the synthetic mesh and the use of synthetic mesh in pelvic reconstructive surgery, but my question is a little more narrow, and that is do you agree with the opinion that the pores are too small in the Ethicon Prolene® mesh?

MR. ROSENBLATT: Object to form.

A. Right, I don't agree with that. And the reason is that the Prolene® mesh is a macroporous Type 1 monofilament material that undergoes excellent integration into patients' tissues, which I have seen on countless cases, and I think it's completely appropriate and probably the most appropriate in that it also has great qualities in terms of being tension free and not moving and incorporating well into tissue.

Q. You said that it has a history of excellent integration into human tissue?

A. Correct.

Q. Does that happen 100 percent of the time?

A. What I have seen in my own clinical practice is that it does. I mean, can you get exposures, yeah, that's possible.

Fortunately, you know, Prolene® mesh which is used for slings such as TVT and TVT-O has an extremely low exposure rate of about 1 percent, and so, you know, I guess those are the exceptions when you don't get tissue integration. But for the vast majority of cases, there's excellent integration with the tissue.

Q. But there are cases where that doesn't occur?

A. But that can also occur with Prolene® suture, and there are, you know, mesh -- you know, suture exposures in the vagina that happen with suture, and the suture has been around for over five decades.

So, yes, there are always going to be exceptions, but when you think of the 99 percent of women whose lives have been improved

from this one device, there's no comparison. There's no other procedure that's been as successful to help women with these problems.

Q. I'll respectfully object to the non-responsive portions of the answer other than, yes, there are exceptions.

MR. ROSENBLATT: Doctor, you can answer however you see fit.

Q. And you know I mean no disrespect by those objections.

A. I understand. I appreciate that.

Q. I have to respectfully move to strike portions of your answers that I don't believe are responsive to my questions.

You understand that, right?

A. I do understand that.

Q. You've been deposed before, haven't you?

A. I have.

Q. That doesn't hurt your feelings, does it?

A. No, not all. Thank you for saying that.

Q. I'll represent to you that Dr. Rosenzweig also holds the opinion that

polypropylene mesh is not suitable as a permanent implant due to its heavy weight.

Does the weight of polypropylene mesh have a bearing on whether or not it's suitable for use in pelvic reconstructive surgery?

A. So I respectfully disagree with his opinion that it's a heavy weight mesh. It is considered a lightweight mesh by the -- you know, by classifications in the urogynecologic literature.

Q. Is there something known as old mesh as opposed to new mesh?

MR. ROSENBLATT: Object to form.

A. I haven't heard that specifically, those terms.

Q. You've never seen the internal Ethicon documents where Ethicon representatives refer to some types of Ethicon mesh as old mesh?

MR. ROSENBLATT: Object to form. Mischaracterization of the documents.

A. I don't recall seeing that, but I'd be happy to look at any documents you want me to look at.

Q. The notion that there's a old mesh

and a new mesh, that's a foreign concept to you as you sit here today?

A. Well, I can imagine what you're referring to.

You know, for instance, I think of -- you know, polypropylene mesh is like Marlex® mesh, being a heavier mesh than the current meshes, but I would consider Prolene® mesh, which is the mesh used for TVT and TVT-O and TVT Abbrevo, for instance, and TVT Secur as being a newer lightweight Type 1 macroporous monofilament mesh.

Q. Okay. That stated, do you believe that the weight of a mesh, synthetic mesh, would have a bearing upon whether or not it's suitable for pelvic reconstructive surgery?

A. So taking with what I said that these are considered lightweight meshes, I suppose that you could have heavier meshes than what we're talking about that may not be appropriate, but I'd have to know exactly which meshes you're referring to.

Q. Well, in what ways can you conceive of that a heavier mesh would be inappropriate for an implant?

MR. ROSENBLATT: Object to form.

A. Well, bearing in mind that we're not talking about the meshes that I just described, you know, if you had a mesh which had extremely limited pore size, that might affect the ability of the mesh to incorporate. And in my mind, you know, I'm not thinking about specifically Ethicon meshes, but I think of other meshes that are, for instance, woven, like the IVS mesh or the ObTape which are much less porous, and so I guess I'm thinking about those being heavier meshes which did have issues with them.

Q. The heavier the mesh, the smaller the pore size?

MR. ROSENBLATT: Object to form.

A. Not necessarily, right? You can have a very wide open weave with, depending on what the weave is, with a heavier mesh, with a heavier diameter of the strands. So I don't think there's a direct correlation between the diameter of the strands and the pore size.

Q. Do you believe that the smaller the pore size, the more problems it can create for the woman?

MR. ROSENBLATT: Object to form.

A. No, I think what the literature shows and mesh science shows is that if you have microporous mesh it's possible that you may not -- for instance, you may not get good tissue integration throughout the mesh, but also, the possibility that bacteria could get into the interstices of the mesh and the body's ability to fight those bacteria with macrophages might be compromised, but I don't think that has anything to do with the Prolene® mesh that we're talking about.

Q. I'll represent to you that Dr. Rosenzweig holds the opinion that polypropylene is not suitable as a permanent implant because it causes chronic foreign body reactions.

Do you agree with that?

A. No.

Q. Why not?

A. There are many implants that are used throughout surgical interventions, including anything from artificial hips to pacemakers to mesh, to hernia mesh, which incite a foreign body reaction. That's a normal response of the body

to a foreign object. That doesn't translate -- there's no correlation between that and the development of problems such as, you know, pelvic pain or dyspareunia. So it's sort of apples and oranges. Just because you may get a foreign body reaction does not mean that's an untoward effect toward the implant.

Q. Is there a difference between a transitory foreign body reaction and a chronic foreign body reaction?

A. I believe it is possible to get a transient versus a permanent, a foreign body reaction, but that again doesn't translate into a clinically significant problem.

Q. What is the difference between -- I'm using the word transitory, and you said transient. Am I calling it the wrong thing?

A. I believe that those are synonymous.

Q. Okay. I'm just going to say transitory because that's how I know it.

A. Okay.

Q. Is there a difference between a transitory foreign body response and a chronic foreign body response?

A. Well, I think the way you're using it and the way I'm using it I believe that one with time it tends to go away, and one would be sort of a permanent reaction, but I'm not aware of any literature that shows that that translates into a clinical difference for the patient.

Q. When you're talking about foreign bodies inserted into a woman's vagina, is the difference between a transitory foreign body response and a chronic foreign body response a significant distinction to make?

A. From a clinical standpoint, I don't believe that's true.

Q. Why not?

A. Because I don't know any literature that has shown that to be the case.

Q. You don't know of any literature that shows that synthetic transvaginal mesh causes chronic foreign body reactions?

A. That's not what I said. What I'm saying is that has not translated into a clinically significant difference, whether it's chronic or transitory.

MR. ROSENBLATT: Once you finish this line of questioning, if we could take a

break.

Q. Help us understand what you mean by clinical difference.

A. In other words, what is the difference for the patient, that's what I mean by clinical difference.

In other words, if you take biopsies and you show that there's a chronic versus a transitory or transient foreign body response, that doesn't translate or correlate with a patient's symptoms, so it may be inconsequential, even though on a pathological report you may see a chronic foreign body response versus one that's transitory.

Q. So you don't think it's a more serious issue for a woman to be facing a chronic foreign body response than it is to be facing a transitory foreign body response?

A. I have not seen literature that suggests that a chronic foreign body response translates to a clinical difference for a patient.

Q. Well, a chronic foreign body response could be recurrent infections for a woman who's having foreign body response to

something that's been implanted into her vagina?

A. Right, so fortunately infection of mesh that we use in the vagina for either slings or prolapse is exceedingly rare, and I can think of -- of the over 2,000 slings or mesh that I've put into a woman, I can think of one case where an infection required me to remove the mesh. That's a very low percentage.

Q. You have had a patient who had a chronic foreign body response to transvaginal synthetic mesh that required you to go in and remove the mesh because it caused recurrent infections?

MR. ROSENBLATT: Object to form. Misstates the testimony.

A. Yeah, that's not what I'm saying at all.

Q. I'm trying. I'm trying.

A. Okay. It actually wasn't recurrent infections. It was a patient who had a TVT-O obturator sling who within the first week of surgery developed a serious infection which required me to remove the mesh probably within four days of the insertion.

Q. What caused that infection?

A. The causative agent was I believe Group A Strep which is a very serious infection.

Q. Do you have any idea how that mesh got infected with the Strep?

A. No.

Q. Based upon a reasonable degree of medical probability, did it occur as the mesh was being inserted into her vagina?

A. I think that's a reasonable assumption.

Q. In other words, did it pick up some Strep on its way in?

A. I believe that's reasonable, but that's exceedingly rare.

MR. CRAWFORD: You want to take a break?

MR. ROSENBLATT: Yeah.

(A break was taken.)

BY MR. CRAWFORD:

Q. Doctor, we are back from a break. At the risk of beating a dead horse, we have to talk just a little bit longer about this transitory versus chronic, okay?

A. Sure.

Q. To let you know where I'm coming

from, I'll represent to you the plaintiffs in this case are going to criticize Ethicon for warning physicians that their synthetic mesh could cause a transitory foreign body response but not going that extra step and advising it could cause a chronic foreign body response.

Do you follow me so far?

A. Yes.

Q. I gather from your testimony that you don't think that's a fair criticism.

A. I agree.

Q. Why?

A. From what I've already stated, which is that that does not -- I've never seen any literature or in my personal experience doing this for, you know, 20 years that any kind of response to a foreign material translates into a clinically significant problem, and I'll give you an example. We implant -- we implant pacemakers. I'm not talking about cardiologists. I'm talking about urogynecologists implant pacemakers for overactive bladder, for fecal incontinence, for urinary retention. That's a foreign body. The body responds to that by walling off the device, and I guarantee you a metal pacemaker is not

porous. So you get a walled off -- you know, that's one response to a foreign body. You may do pathologic studies, if you want, and show that you may have a chronic foreign body response 'cause the body sees that has a foreign body. Patients are asymptomatic. It's irrelevant what the body is doing as long as the patient doesn't have a bad reaction to it, clinically.

Q. And I think that's the point is -- I think what we're doing is equating chronic foreign body responses to chronic recurrent infections in women.

A. When you say "we," who are you talking about?

MR. ROSENBLATT: Object to form.

Q. Is it fair to equate chronic foreign body responses to chronic recurrent infections in these women?

A. No, it's not fair because a foreign body response has nothing to do with infection. That would be a chronic infection. That's not the same thing as a chronic body reaction.

Q. The body's reaction to a foreign body is inflammation, right?

A. Usually initially.

Q. And what else? Strike that.

How does the body respond to a foreign body?

A. In many different ways, but often it's with fibrosis, but you know, you get fibrosis just with any surgery in the body. You know, think of a scar on your arm if you cut yourself or a keloid, that's scar tissue. So that's a normal response to healing.

Another normal response in this case to a foreign body is to try to wall off the foreign body or try to cause scarring or fibrosis around the foreign body, and that is a foreign body response. That doesn't mean it's a bad response. That's a pathologic diagnosis. But we know, and in this case, we have literally millions of women who've had the surgery, and it's done -- you know, and it's been so beneficial for these women. So having a foreign body does not mean that it's a bad response of the body to a foreign material.

Q. Move to strike the non-responsive portions of that answer.

A foreign body response is not necessarily a bad thing, correct?

A. Right, and also, it doesn't equate to infection.

Q. A foreign body response is not a bad thing, correct?

A. Correct.

Q. Unless it creates symptoms for the woman.

MR. ROSENBLATT: Object to form.

A. Well, I think there's -- I have to disagree.

Q. Okay.

A. There's a foreign body response, but then there are possibly effects that are separate from that foreign body response such as exposure. Exposure of mesh which can occur doesn't mean that it happened because of a foreign body response. Exposures can be caused by other things like a hematoma or a suture line that opened up. So I think what you're doing is equating a foreign body response with chronic infection, and that's just not -- that's just not how it happens.

Q. What about -- what about equating a chronic foreign body response to chronic symptoms such as pain, dyspareunia, and -- go ahead.

MR. ROSENBLATT: Object to form.

A. So I'm glad you brought that up. And there was -- there are studies that have looked at this. I can't remember what the first author's name is, but there was one study which was a great idea. They removed pieces of mesh from women who needed a revision of their slings, which is not that unusual, right?

So someone who develops urinary retention or overactive bladder or some other type of voiding dysfunction occasionally -- you know, I do these surgeries -- we have to bring women back for revision of the mesh which is usually just cutting the mesh.

What these researchers did was to take out a portion of the mesh and look at it under the microscope, send it to pathology. And they actually found that the women who had their mesh removed for voiding dysfunction had more foreign body reaction than the women that had pain. So there was no correlation between foreign body reaction and pain. There was actually more foreign body reaction with voiding dysfunction. So you cannot equate pain with foreign body reaction.

Q. You cannot equate pain with a foreign body response to synthetic mesh?
A. Correct.
Q. What study were you just referring to?
A. I don't remember the first author, but I'm happy to --
Q. Well, there's been several times where I've said, nah, you don't have to look that up, but that was a pretty significant answer, so I'd like to know the name of that study.
A. Okay.
MR. ROSENBLATT: We can try to get it during a break.
MR. CRAWFORD: Okay, that sounds good.
A. I'll make a note.
Q. Dr. Rosenswine -- excuse me. Dr. Rosenzweig --
A. Is that a Freudian slip?
Q. Dr. Rosenzweig opines that Ethicon's Prolene® mesh is not suitable for permanent implant because the material safety data sheet for polypropylene resin used to make polypropylene states that it's incompatible with

strong oxidizers such as peroxides which are readily found in the vagina.

Is he wrong about that?

A. I don't agree with his statement at all for several reasons.

One is that Prolene® mesh is simply made up of polypropylene fibers which we've been using for over 50 years. I've gone back in on a personal, you know, anecdotal level, and I've seen Prolene® sutures that have been placed a decade before I've been there, and I've seen no evidence of any degradation of the Prolene®. I've removed Prolene® mesh before and have not seen any degradation of the mesh.

And in addition, and I can't speak for all polypropylene, but I know with Prolene® that there are specifically antioxidants that are proprietary that resist oxidation.

Q. So the basis for your opinion -- strike that.

The basis for you disagreeing with Dr. Rosenzweig's opinion is that you've seen polypropylene sutures in women that have been there for a long time and they hadn't oxidized or degraded, therefore other synthetic meshes

shouldn't oxidize or degrade; is that right?

MR. ROSENBLATT: Objection to form.

A. No, that's one example, but also, I'm familiar with the literature that has looked at this. I'm familiar with the scanning electron microscopy which in some people's eyes has looked like it has shown evidence of cracking and degradation, but I'm also familiar with other studies that have shown that that's a biofilm, that the cracking is not in the polypropylene itself, and if you wash it away, you get pristine polypropylene. So I am not aware of any definitive literature in humans that has shown that there's degradation from oxidation of Prolene® mesh.

Q. I got to go back and clean that up a bit.

Dr. Rosenzweig opines that Ethicon's Prolene® mesh is not suitable for permanent implant because the material safety data sheet for polypropylene resin used to make the mesh said it's incompatible with strong oxidizers such as peroxides which are readily found in the vagina. And you disagree with that opinion, correct?

A. Correct.

Q. And one of the reasons that you disagree with that opinion is because you're unaware of any medical literature that indicates degradation due to oxidation of polypropylene mesh?

A. No, I said of Prolene® mesh.

Q. I'm sorry. Prolene® mesh.

A. Correct.

Q. The other reason that you disagree with Dr. Rosenzweig's opinion on that is because you, yourself, have seen Prolene® sutures in patients of yours that have been there for years, if not over a decade, and they weren't oxidized or degraded?

A. So not only Prolene® sutures but also Prolene® mesh.

Q. Used to treat?

A. Stress incontinence.

Q. What does it mean for something to be cytoxic? Cytotoxic. Excuse me.

What does it mean for something to be cytotoxic?

A. My understanding is that it would be toxic to cells.

Q. If a material is cytotoxic, does that mean it can cause cell death and complications?

MR. ROSENBLATT: Object to form.

A. I believe the definition of cytotoxicity is death to cells.

Q. Dr. Rosenzweig opines that Ethicon's Prolene® mesh is not suitable for permanent implant in women because it's cytotoxic. Do you agree with that?

A. I have not seen any literature that would substantiate that claim.

Q. If there was credible scientific evidence that polypropylene is cytotoxic, would that render it not suitable for permanent implants in women?

MR. ROSENBLATT: Object to form.

A. No, I think it would have to have some clinical significance.

And again, let's go back and state, as I did earlier, that we've been using polypropylene and Prolene® sutures for decades, and I'm not aware of any untoward effects that that might have of any clinical significance, and you know, you've got -- you've got several

million women that have benefited greatly from this technology over a period of, you know, over 17 years, probably more like 20 years at this point including Europe, and I think that's sort of a ridiculous statement because we just don't see that clinically.

Q. Move to strike after the first reference to clinical significance.

MR. ROSENBLATT: Doctor, you can answer however you see fit.

Q. What condition is the Burch procedure designed to treat?

A. Stress urinary incontinence.

Q. Do you agree that although the Burch procedure may take longer and require a short hospitalization, it's a safer procedure than synthetic slings?

MR. ROSENBLATT: Object to form.

A. I disagree with that statement.

Q. Why?

A. First of all, I do Burch procedures. I've been doing laparoscopic Burch procedures since 1993. I think it's a very good procedure to treat stress incontinence, but the long-term results are not as good as with

midurethral slings, and you open up a whole host of other potential complications that are not seen with midurethral slings.

Q. What are those?

A. Well, there's, you know, in general the risk of general anesthesia. So if you do a laparoscopic Burch, you really need to use general anesthesia, so that increases the risk compared to doing a midurethral sling under local anesthesia with conscious sedation.

Now, you're also getting intraperitoneal with a laparoscopic Burch or an open Burch, so there's the potential of major vascular injury. There's the potential of a bowel injury. And although, you know, theoretically you could get a bowel injury with a midurethral sling, it's exceedingly rare. It's an incredibly low number.

And, you know, any time you do general anesthesia and you take longer, there are always going to be inherent risks of DVTs and, you know, aspiration and et cetera.

So I think midurethral slings have been shown to be a much safer alternative than the Burch. That said -- may I continue?

Q. Of course.

A. I'm doing some more of them these days just because of all the, again, fear mongering, that women come in and have a -- they're afraid of mesh. And so even after talking to them, some women will prefer, honestly, to have the old-fashion Burch, which is a very good procedure, but I don't think it's as good as a midurethral sling.

Q. Move to strike the reference to fear mongering.

A. I like that.

Q. Me, not so much.

The Burch procedure is a very good procedure to treat stress urinary incontinence, correct?

A. Yes.

Q. You perform Burch procedures to this day, correct?

A. Correct.

Q. In fact, you perform more Burch procedures now than you use to.

A. No.

Q. No?

A. No. You know, back in 1995 when I

first started my practice, that was -- 90 percent of my anti-incontinence operations were laparoscopic Burch.

Q. You're performing more Burch procedures in recent years than you use to, correct?

A. Slightly more, yes.

Q. The reason you're performing more Burch procedures in recent years is due to fear of complications by the general public concerning the use of polypropylene mesh slings, true?

A. No. It's because of patient's anxiety seeing ads on TV and what they read in the internet about transvaginal mesh, and they equate midurethral slings with transvaginal mesh, and some women will come in with an attitude, please do not talk to me about using any mesh in the vagina.

Q. Does that irritate you when that happens?

A. I think irritate's the wrong word. I think -- you know, I'm -- I think it's a shame that women have -- you know, that women are being exposed to this because first and foremost my goal is to take care of my patients and to offer

them the best treatment possible.

Although I think a Burch is a good procedure, I don't think it's the best treatment possible, and I think what we're going to be seeing are more patients coming back with recurrences of their stress incontinence, and you know, I hope that's not the case, but I do know it's the case just if you look at the literature. Ultimately there is a decrease in the efficacy of a Burch procedure over time.

Q. Over what period of time?

A. Well, certainly, you know, the early studies on comparing Burch with TVT are similar, but as you get out to about five years, seven years, there's a significant decline, and there are studies even going out 15 years that -- you know, whereas when you do a midurethral sling, it's pretty rare for a patient to come back and say, you know, that sling worked for a couple of years and now it's not working. It really is consistent. But with Burchs, I'm seeing patients I operated on 20 years ago who are coming back saying, yeah, I got that stress incontinence again, what can you do for me now?

Q. Do you agree that if complications

do occur following a Burch procedure they're rarely long-term and they're easy to treat?

A. Well, again, if you consider failure, you're talking about a whole another operation for their stress incontinence. I've seen ureteral injuries. In fact, I've published on a ureteral injury after a Burch, where I've never seen a ureteral injury after a midurethral sling. In fact, I'm not even aware that it's ever been -- I'm not sure if it's ever been reported, but certainly I've never had that experience. But failure is not to be taken lightly, and to me, that is a complication because it requires the patient undergo another operation.

I've also seen urinary retention after a Burch, although, you know, obviously you can see that after any anti-incontinent operation, but to relieve urinary retention after a sling is much easier than to relieve urinary retention after a Burch.

Q. What's the most common complication resulting from a Burch procedure?

A. I would have to say voiding dysfunction.

Q. Is that easy to treat?

A. Well, sometimes it will manifest -- it can be treated just with time and with catheterization, but occasionally you have to go back in and remove the stitches, and that would require another general anesthesia, entry into the space of Retzius and literally cutting the sutures, and I've had to do that a couple times.

Q. And that's what you would consider a complete fail, a complete failure of the Burch procedure?

A. I mean, to me -- in my mind, a failure of the Burch is when it doesn't treat the stress incontinence which is about 15 percent of the time, so. Yeah, about 15 percent of the time. As opposed to a failure versus a complication. So I look at them differently, you know, yeah.

Q. What percentage of Burch procedure patients require another surgery?

MR. ROSENBLATT: Jeff --

Q. Strike that. What percentage of Burch patients have their procedure fail thus requiring another surgery?

MR. ROSENBLATT: Are we going to

count this as his TVT general depo as well?

MR. CRAWFORD: Sure.

MR. ROSENBLATT: All right.

A. So what most people will quote in the literature is that the success rate, meaning, you know, successful treatment of stress incontinence, is about 85 percent with a Burch whether it's done open or laparoscopic.

Q. When Burch procedures fail completely, typically how long after the surgery does that occur?

A. It's variable. So it can occur immediately if you don't tension the sutures correctly, and that's really done by surgeon judgment. You know, it's a kind of -- Gestalt. I don't know how to spell Gestalt. Anyways. But over time because we're just dealing with sutures, that can tear through.

And by the way, we are talking about permanent sutures, whether they're Prolene® or GORE-TEX, but there is a -- you know, if you look at like a Kaplan-Meier survival curve. So that when you start out with all the patients that are successful over time, the survival curve, meaning, you know, failure, does continue

to grow with advancing time up to, you know, 15, 20 years.

Q. And I understand there's variables and there's a range, but if a woman were to peek her head in the door right now and say, Doctor, I've got stress urinary incontinence, I want to undergo a Burch procedure, if it fails typically how long after the surgery will it fail?

A. So it can either be immediate, right, because of 85 percent success, and 15 percent of women will come back and say, you know, it just -- it isn't working. I mean, this to me, it's like Goldilocks, right. So it's either too tight, which puts you into retention. Too loose, and you're in the 15 percent that have, you know, quote/unquote, failed. Or it's just right, which is, you know, the 85 percent range. But typically, in my experience, that we may see people five years out, seven years out who are coming back saying it worked, but you know, now I've got stress incontinence again.

Q. But would it be fair to say the majority of women whose Burch procedure fails, they know it immediately. You know right away you're not the Goldilocks.

A. So that is a -- I don't know what the breakdown would be, but that can happen, but I've also seen women who after a year or two or three come back with complaints of symptoms, and I think it has to do with not just the way the procedure is performed, but it has to do with the patient's lifestyle, if she's a woman who has chronically increased intra-abdominal pressure, she's an asthmatic, she's a nurse and she lifts patients, she goes to the gym a lot, she's constipated. You know, there are lifestyle issues that can affect the long-term success, so it is very variable.

Q. Do you agree with Dr. Rosenzweig that polypropylene is chemically reactive and not inert?

A. I do disagree with that.

Q. Why?

A. I think most -- the literature that I've read, quality of literature, suggests that polypropylene is for all intents and purposes biologically inert.

Q. What quality literature are you referring to?

A. I've read a number of studies about

polypropylene or Prolene® mesh. I can't quote for you the names, but that discuss the fact that it is biologically inert, and also, in the clinical literature, it is referred to as biologically inert, and I've never seen anything either in literature or in my personal experience that suggests that it's not inert.

Q. I'm really interested to see what quality literature you're referring to that shows that it's inert. Can we look that up on the next break?

A. Yes.

Q. What does inert mean?

A. Non-immunogenic.

Q. What does non-immunogenic mean?

A. Doesn't elicit a immune response of any clinical significance from the host.

Q. In layman's terms, does that mean the body doesn't attack it?

A. Not really. I mean, you know, we talked about foreign body response, but it isn't seen as something that you could -- like a kidney transplant, you know, something that you would develop a severe immune response to that would elicit a severe immune response, basically.

Q. Do you agree with Dr. Rosenzweig that polypropylene can degrade and release toxic compounds into pelvic tissues?

A. No, I don't agree with that.

Q. Why not?

A. Well, I've never seen any evidence that there's any clinical significance that there are any toxins released. I'm not aware of any literature that I've reviewed that suggests that.

Q. I think we may have touched on this already, but it will only take a second.

Do you agree with Dr. Rosenzweig that polypropylene mesh can oxidize inside the vagina thus causing the mesh to degrade, crack and break apart?

MR. ROSENBLATT: Object to form.

A. So are we talking about polypropylene or Prolene®, first?

Q. Polypropylene.

A. So I have not seen evidence of that, and I've read the literature, you know, the biochemistry, as we've discussed, some people suggesting that there's cracking, surface cracking, but other excellent evidence that I've seen that shows that that's a biofilm, that's an

artifact of the preparation of the material, and that if you do a proper washing of that, you'll seen pristine polypropylene without any evidence of degradation or oxidation. And in addition, you know, with the mesh that we're talking about here, which is Prolene®, has additives that are antioxidants.

Q. Are you aware of any literature that indicates polypropylene mesh can oxidize inside the vagina, thus causing mesh to degrade and crack and break apart?

A. So I have seen literature, but there seems to be two schools of thought, and the, quote/unquote, artifacts that I've seen with scanning electron microscopy, appear to be just that, where it's not the cracking of the polypropylene material but of a biofilm that is on top of the polypropylene.

Q. To be clear, you have seen literature that indicates polypropylene mesh can oxidize inside the vagina, thus creating or thus causing it to degrade, crack and break apart?

MR. ROSENBLATT: Object to the form.

A. The literature I've seen is

interpretation of scanning electron microscopy but not that proves that degradation or cracking exists.

Q. Are you aware of any changes Ethicon has made to Prolene® mesh since it was introduced to the market?

A. Are we talking about Prolene® suture or Prolene® mesh?

Q. Mesh.

A. The only thing that I'm aware of is the way that it's, the Prolene® mesh, is cut.

Q. What change was made?

A. Well, it was being offered initially as mechanically cut, and then it was being offered both as mechanically -- mechanical or laser cut. I'm not aware of any other changes.

Q. Which came first, mechanically cut mesh or laser cut mesh?

A. I believe mechanically cut.

Q. Do you know why they started making it laser cut as opposed to mechanically cut?

A. I believe it was -- it simplified the manufacturing process, I believe. I believe I heard that.

Q. Are you aware of any reasons why Ethicon began to cut its polypropylene mesh using lasers, as opposed to mechanically, other than because it simplified the manufacturing process?

A. No, I'm not aware.

Q. You've never heard it said that laser cut polypropylene mesh is safer than mechanically cut polypropylene mesh?

A. No.

Q. You never heard it said that laser -- there's less complications with the use of laser cut mesh as opposed to mechanically cut mesh?

A. No. You know, that may have been said by a plaintiff expert opinion, but you know, I've had experience with both. I can tell you from my personal experience I've not noticed any difference, and I haven't had, you know, any change in complications going from one type of cut to another. Nor am I aware of any literature that shows there's a difference.

Q. Is another way of saying that you're unaware of any clinical difference between the use of mechanically cut mesh and laser cut mesh?

A. Correct.
Q. Are you aware of any internal studies performed by Ethicon in which scientists working for Ethicon concluded that Prolene® can degrade while implanted in the human body?
MR. ROSENBLATT: Object to form.
A. I am not aware of any such studies. Is that the word you used?
Q. Yes, sir.
A. No.
Q. You're unfamiliar with a study in 1987 where Ethicon scientists found that Prolene® degrades?
MR. ROSENBLATT: Object to form.
A. I have not seen that study.
MR. ROSENBLATT: Do you want to show it to him to see if he's seen it?
Q. Do you know whether Ethicon was advised by an outside consulting group in June of 2011 that an animal study showed polypropylene can degrade following an implant?
A. Did you say an animal study?
Q. Yes, sir.
A. I don't recall seeing that, but I'm not sure what significance that has coming from

an animal study.

Q. Move to strike after "don't recall seeing that."

Are you aware of a 2009 presentation in which Ethicon Medical Director Piet Hinoul stated that meshes are not biologically inert?

MR. ROSENBLATT: Object to form.

A. I may have seen something to that effect, but I don't agree with that. And are we talking about in humans or in animals?

Q. Have you ever opened an Ethicon mesh product and found that synthetic mesh inside is broken, cracked or brittle?

A. No.

Q. Doctor, I'm referring to Exhibit No. 2, specifically page 43 of Dr. Rosenzweig's report, and this particular page bears two images of what appear to be blue mesh.

Do you see those?

A. Yes.

MR. ROSENBLATT: And this is Rosenzweig's TVT report?

MR. CRAWFORD: Yes, it is.

Do those images appear to reveal

particles of the mesh that have begun to break off inside the package.

MR. ROSENBLATT: Object to form. Lack of foundation.

A. So I don't know what you mean by broken off, but it looks like there are small pieces of polypropylene fibers that are separate from the body of the mesh.

Q. Have you ever opened an Ethicon product and seen mesh that looks like that?

A. I don't recall ever seeing that, but if I did see that, that wouldn't bother me at all.

MR. CRAWFORD: Move to strike after I don't believe I've ever seen that.

Well, let me ask you, if you were to open a package of Ethicon mesh and it were to look at that, would that bother you?

A. Not at all.

Q. Why?

A. We leave sutures in people's bodies, permanent sutures, all the time. We've done it for decades. We leave surgical metal clips in people's bodies all the time. There's no evidence that I'm aware of that small pieces

of suture, basically that's what that is, would cause any untoward effects.

So to me that looks like an artifact of the cutting process, that when you cut it either -- I don't know if that's laser or mechanical, but there will be little pieces of suture that may be inside the body. Obviously, those pieces have fallen off, and they're not going to be implanted. But even if a mesh did that and little pieces came off, it would be inconsequential. That wouldn't affect anything.

Q. 100 percent of the time?

A. 100 percent of the time.

Q. All right. Did you say there's been other operative procedures where you've left things, foreign bodies, in people's body?

A. Yes. Not me, every surgeon.

Q. What kind of stuff?

A. Surgical titanium clips, float rings, which are, you know, for tubal ligation, sutures. That's a part of doing surgery.

Q. And you've never heard of anyone -- you've never heard of an instance where a surgeon has inadvertently left a foreign body in someone after a surgery and it caused horrible

complications?

A. I didn't see that. I mean, you wouldn't like to leave like a clamp inside someone's body. You wouldn't want to leave a sponge inside a body or a retractor. All those things have been left in people's bodies. But things that we just talk about like suture that are covered inside the vagina or inside the body are inconsequential.

Q. 100 percent of the time?

A. Well, I just gave you an example of things that you wouldn't want to leave inside the body, but I don't see any issue with a piece of mesh or, I'm sorry, a piece of suture of that magnitude causing any problems. I've never ever seen that in 20, 21 years of practice.

Q. How many times over the course of your practice have you seen a suture inadvertently left in someone's body following a surgery? Not a suture. What else did you say was inconsequential? You likened the suture to --

A. Clips.

Q. Clips. Thank you. How many times over the course of your career have you seen

clips inadvertently left in someone's body and there be no consequence?

A. When you say inadvertently, you're saying not on purpose.

Q. Yes, sir.

A. Oh, that's not what I'm talking about. I'm talking about clips for bleeding. So they're not inadvertently. They're done on purpose. But they're left. And if you take a x-ray of countless women, you'll see little metal clips throughout their body. You know, that's a common occurrence. And most surgeons don't even tell their patients that they have these clips in them. That's just sort of a -- you know, that goes along with having surgery. Excuse me, one second. Okay. And, you know, I've not seen that cause any untoward effect.

Q. Hypothetically speaking, if there were credible scientific evidence that Ethicon Prolene® mesh degrades in the human body, would that make it unsuitable as a permanent implant for stress urinary incontinence?

MR. ROSENBLATT: Object to form.

A. I guess, again, you'd have to look at, you know, whether it's clinically

significant. In other words, let's say you used absorbable material for a sling, like, you know, polyglactin. That is meant to degrade. It's meant to be hydrolyzed and get absorbed. But if the woman were continent afterwards, it would be inconsequential. But, you know, I've not seen evidence of degradation of the Prolene® mesh, but if it did degrade but it wasn't clinically significant, it wouldn't matter.

Q. If Ethicon became aware of credible scientific evidence that polypropylene has the potential to degrade, would you, as a practicing physician, expect them to conduct relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene degradation?

MR. ROSENBLATT: Object to form.

A. I guess it would have to be -- there would have to be some clinical significance associated with it. It would have to -- to me it would have to cause some harm to the patient, and without that, it would be inconsequential.

Q. A recurring theme that I'm hearing and correct me if I am wrong, but a recurring theme I keep hearing in your testimony is that it

doesn't matter if the polypropylene degrades inside the human body if there's no symptoms due to it. Is that fair?

MR. ROSENBLATT: Object to form. Misstates the testimony and assumes that degradation does occur.

A. Well, I was actually going to say exactly that which is, you know, I don't see any credible scientific evidence that there is any degradation of Prolene®. And again, which we have already talked about, Prolene® mesh is just made up of Prolene® fibers that have been woven together, and we have literally a half a century or more of data and clinical experience with Prolene®. So I'm very comfortable that it doesn't degrade. But there would have to be some clinical significance for it to be reportable to physicians. And, you know, what we've seen with TVT slings is an operation that is better than any other operation known to mankind in the history of man -- in the history of women for treating stress incontinence. There is nothing better. It has revolutionized the field of urogynecology, that's a fact. And our world changed in 1999 or 1998 in the United States when

that technology came here, and I'm not being -- I'm not speaking with hyperbole. That was one of the greatest things that have happened in the field of urogynecology for our patients. So I don't see any evidence of there being a problem with it.

MR. CRAWFORD: Objection as non-responsive and move to strike.

Is there a difference between pores in the mesh and interstices?

A. There is. Pores usually refer to the large holes, for lack of a better word, that you can see with the naked eye, where interstices refers to the smaller holes within the weaving of mesh.

Q. Does the weave of Ethicon's Prolene® mesh produce very small interstices that allow bacteria to enter and hide from the natural body defenses that are designed to eliminate them?

MR. ROSENBLATT: Object to form. Lack of foundation.

A. Yeah, fortunately -- no, it's not true, in that, and I think it is because of the fact that polypropylene is a monofilament, that

even the smaller interstices are large enough to allow macrophages to get in between where bacteria potentially are, and that's evidenced by the fact that we don't see infections, you know, we don't see -- we don't commonly see infections in this mesh even when it's placed transvaginally.

Q. Does bacteria that's caught up in transvaginal placed pelvic mesh secrete a slimy biofilm that serves to protect and shield the bacteria from destruction by white blood cells?

MR. ROSENBLATT: Object to form.

A. I don't know if that's a -- I actually -- I'm actually not sure where the biofilm comes from, if that's secreted by bacteria or it's from the host response, yeah.

Q. Following the placement of transvaginally placed pelvic mesh, does there appear a slimy biofilm that serves to shield the bacteria from destruction by white blood cells?

MR. ROSENBLATT: Object to form.

A. I think it's been shown that there can be a biofilm. I don't know if that happens all the time. And, you know, again, we have to come back to it being -- whether or not it's

clinically significant, and for someone who has placed over 2,000 slings, and I've only had one serious infection, I think Prolene® mesh is incredibly resistant to infection.

MR. CRAWFORD: Objection as non-responsive. Move to strike everything after "happens all the time."

Does the biofilm that surrounds the pelvic -- strike that.

Does the biofilm that surrounds the transvaginally placed pelvic mesh increase the foreign body reaction?

MR. ROSENBLATT: Object to form. Lack of foundation.

A. I am not aware of that.

Q. Can you say one way or the other whether it does?

A. No.

Q. Do you agree with Dr. Rosenzweig when he says fibrotic bridging occurs when the fiber surrounding the mesh -- strike that.

Do you agree with Dr. Rosenzweig when he says the fibrotic bridging occurs -- God dang. It's getting later. Strike it.

Do you agree with Dr. Rosenzweig

when he says fibrotic bridging occurs when the fibers surrounding the pores of the mesh are too close together to allow the tissue in the pore space enough room to recover from the trauma of tissue damage due to implanting a surgical prosthetic device?

MR. ROSENBLATT: Object to form.

A. I'm not actually sure what he's referring to because there -- though I'm very familiar with the concept of fibrotic bridging, I haven't heard of that being an explanation of recovering from the inflammation. I just haven't heard that argument, nor have I seen that, you know, clinically.

Q. Dr. Rosenzweig opines that small mesh pores that cause fibrotic bridging turn the mesh into a solid sheet of scar tissue, then there's no room for the tissue to grow into the mesh. Do you agree with that?

A. I don't agree with that.

Q. Why not?

A. Well, if the mesh is placed correctly, which is in a tension-free fashion, there's plenty of space between the pores to prevent fibrotic bridging.

Q. Have you ever seen a video of Ethicon consultant Todd Heniford saying, quote, there's no excuse for using heavy weight, small pore meshes in the human body, closed quote?

MR. ROSENBLATT: Object to form, lack of foundation.

A. I have not seen that video, but I can't imagine why that would ever have any relevance to what we're talking about and the types of meshes that we're talking about today.

MR. ROSENBLATT: Just so you know, Jeff, that video was not any of Ethicon's meshes.

MR. CRAWFORD: I'll object as non-responsive and move to strike after "have not seen it."

Thanks, Paul.

Do you agree with Dr. Rosenzweig that polypropylene mesh is known to contract or shrink once it's put into the human body?

MR. ROSENBLATT: Object to form.

A. So in my experience, I have not seen that clinically in my patients.

Q. To be clear, you've never once in all of your years of clinical practice seen a patient where their polypropylene mesh had

contracted or shrank inside their body?

A. So no. I have seen patients who have come in where -- in patients who have had mesh placed with someone else where it seemed like the mesh had a smaller surface area than what you'd expect to see. But there are a couple of issues there. One is that mesh does not shrink. There's no contractile elements within a mesh. The body reacts to surgery and could react around a mesh to contract, that's why even native tissue repairs you get some vaginal foreshortening and you get vaginal scarring, that's a natural occurrence. And if the mesh happens to be there, it will take up less space. But what I've experienced would be, you know, with hundreds and hundreds of transvaginal meshes, is that there's no clinically significant shrinkage that occurs when a mesh is placed correctly.

Q. Since you are of the opinion that mesh does not shrink, am I safe to assume you dispute that shrinkage was known by Ethicon as early as 1998 in published works by Ethicon's many consultants, Uwe Klinge and Bernd Klosterhalfen?

A. So I am aware of that, and I have seen those reports, but the first part of your statement was that I don't believe that mesh shrinks, and mesh does not shrink. There's no such thing as mesh shrinking. It's not like you put it in a dryer like, you know, a shirt in a dryer and it gets smaller. It's the fibrosis that occurs as a natural healing process of surgery that causes shrinkage. Because as I said, native tissue repairs you can get stenosis of the vagina, you can get foreshortening of the vagina. Mesh does not shrink. So if there is any decrease in the surface area of the mesh, it's not from the mesh itself. It's the tissue around the mesh.

MR. CRAWFORD: Object and move to strike the non-responsive portions of that answer.

You are familiar with the Klinge and the Klosterhalfen study.

A. Yes.

Q. And you're aware that they noted in their paper that polypropylene mesh shrinks 30 to 50 percent; is that right?

MR. ROSENBLATT: Object to form.

If you have the paper and you want to put it in front of him, he can take a look at it.

A. Yeah, I was about to say I'd like to see the paper 'cause I want to see if that was from an animal study. I am familiar with the so-called, you know, quote/unquote, shrinkage or contracture in hernia meshes, but I'm almost familiar with literature -- the one that comes to mind is Dietz -- I think it's D-E-I-T-Z or D-I-E-T-Z -- that shows using ultrasound that there is no shrinkage of mesh implanted in humans. So I think that is debatable and controversial.

Q. Do you agree that if there is credible scientific evidence that polypropylene mesh shrinks 30 to 50 percent and as a result there's an adverse clinical effect on the patient, then it's not suitable for its intended application as a permanent prosthetic implant in women?

MR. ROSENBLATT: Object to form. Lack of foundation, compound.

A. What you're suggesting is not the case. You know, and the reason I say that and I'm comfortable saying that is I've been

implanting mesh transvaginally for 15 years, and I do not see that clinically.

Could a particular woman have a fibrotic reaction where she would have had a fibrotic reaction and scarring with a native tissue repair? Yeah, that can happen, and there might be mesh there, but I do not see that -- when you say, you know, if you could show that mesh -- mesh does not shrink. So it doesn't make a lot of sense to me to assume that, you know, mesh shrinks 'cause it doesn't shrink.

MR. CRAWFORD: Objection. Non-responsive, move to strike.

I understand that you've opined mesh doesn't shrink. I'm asking you a hypothetical question, and I'll pose a hypothetical question to you.

If there's -- strike it.

Hypothetically speaking if there's credible scientific evidence that polypropylene mesh shrinks 30 to 50 percent in the human body and that shrinkage results in a clinically adverse effect upon the patient, then it's not suitable for application as a permanent prosthetic implant in a woman.

MR. ROSENBLATT: Object to form. Compound, incomplete hypothetical.

A. So I think that you said if there is credible scientific evidence. I'd want to weigh all the evidence, right. I mean, so you can't cherry pick, and what I mean by that is just -- you know, like, for instance, when I started, and don't object to this, please, but when I started -- hear me out.

When I started doing this work for Butler Snow, I asked them to send me all -- you know, I did my own searches, PubMed search, but they have pretty good resources, too, and I said send me the literature, the good and the bad. Send me the literature that -- for instance, in this topic, this particular topic, if there's literature that shows that there's no shrinkage, like the Dietz article, I want to see the literature that seems to suggest there is shrinkage, and I want to evaluate it. I looked at all of it. I didn't cherry pick to say, okay, that article supports my theory and that's all I'm going to look at. I looked at it all. So there may be an article out there that you're referring to, and I'd be happy to see it, that

suggests that mesh shrinks, but I would want to look at all the data. And if the preponderance of data show that mesh shrinks, then I would have a different opinion, but I don't.

MR. CRAWFORD: Objection. Non-responsive, move to strike.

MR. ROSENBLATT: Want to take another quick break?

MR. CRAWFORD: Yeah.

(A break was taken.)

BY MR. CRAWFORD:

Q. Dr. Rosenzweig has opined that in addition to fraying and particle loss mechanically cut synthetic polypropylene mesh has been shown to rope, curl and deform when it's under tension. Do you have an opinion on that?

A. So maybe I missed the first part of this. Which mesh are we talking about?

Q. Let's go with Prolene® mesh.

A. Prolene®. So I do have an opinion on that and that is under normal clinical conditions you would never put Prolene® mesh, like in TVT or any of those products, under that kind of tension that would cause roping or curling.

If you take a piece of Prolene® sling mesh and pull it really hard, it will turn into a cord, no question about it. You would never ever do that clinically. It just -- it doesn't make any sense. So whether that happens in a bench or you do that in a cadaver, it's clinically insignificant.

Q. To summarize your testimony, it doesn't matter whether Prolene® mesh frays or has particle loss and has been shown to rope, curl and deform when it's under tension because in real-life situations it's never going to be under that kind of tension; is that fair?

MR. ROSENBLATT: Object to form.

A. Not if it's done using the instructions for use the way peer to peer, surgeon to surgeons teach how to perform a procedure, that is not clinically relevant.

Q. Dr. Rosenzweig has opined that characteristics of Ethicon's mesh including particle loss, fraying, roping and curling make it improper for use in the vaginal canal. Do you agree with that?

A. So, again, you mentioned mesh, and just so I know which mesh we're talking about --

Q. Prolene®.

A. Prolene® mesh like in TVT?

Q. Yes, sir.

A. I disagree with it because I think it's completely appropriate for use in the vagina, and that's been borne out after millions of cases.

Q. Do you agree that particle loss and fraying of synthetic mesh can lead to an increased inflammatory response?

MR. ROSENBLATT: Object to form.

A. Again, maybe I'm missing the point, but I think it's my same answer, which is that under normal conditions you would never pull mesh tight enough to cause roping or fraying, and so it's sort of irrelevant. But even if you did have particle loss, those particles are inconsequential clinically.

MR. CRAWFORD: Objection as non-responsive. Move to strike everything other than "if you did have particles" and thereafter.

If synthetic polypropylene mesh were to rope or curl, would that lead to a loss of pore size?

MR. ROSENBLATT: Object to form.

A. Yes, it's possible that if you pull on mesh, which you shouldn't do because -- and it's not just in the instructions, but you know, this is how it's taught, is that you leave these meshes, whether it's prolapse mesh or sling mesh for stress incontinence, in a tension-free manner, then you don't get that reduction in pore size, and you get good -- excellent tissue ingrowth.

MR. CRAWFORD: Objection. Non-responsive, move to strike.

I'm just going to ask you a yes-or-no question.

Do you agree that roping or curling of the mesh, that is the synthetic polypropylene transvaginal mesh, can lead to a loss of pore size?

MR. ROSENBLATT: Object to form. Asked and answered, broad.

A. And I can't answer that yes or no without saying that's clinically irrelevant because you would never pull on it like that, but obviously, if you pull on mesh inappropriately, you will reduce the pore size, depending on the configuration of the mesh.

Q. If a certain amount of tension is put on synthetic polypropylene mesh, can that lead to a loss of pore size.

MR. ROSENBLATT: Object to form.

A. If you put inappropriate tension on a mesh, depending on the configuration of the mesh, the way it's woven, it can lead to a decrease in pore size, that is correct.

Q. I think attached to your report, which is Exhibit No. 1, there's a reliance list. Can you pull that out?

A. This one doesn't have it.

Q. I know I have it in here somewhere.

Were you able to get your hands on your reliance list?

A. Yes.

Q. What is this? What does this list represent?

A. This list represents all the documents and medical literature and other materials that I have relied on for my opinions in my report.

Q. Should someone who is considering your report look at this reliance list and assume that before you wrote your report that you

submitted in this case you sat down and read each and every single one of these documents and watched every single one of these videos in conjunction with writing your report?

MR. ROSENBLATT: Object to form.

A. So many of these articles I've been reading about for the last 15 years. There were some materials in this reliance report that were documents that I scanned that I didn't read every word. There's no way I could have. And there were articles where I scanned but I read the abstracts, but yes, this is all the material that's in there, and I went through it to come up with my opinions.

Q. Turn to the -- shoot, I don't know what page this is. Man, I wish this had page numbers on it.

A. Good point.

Q. I'll start from the back. Flip, one, two, three, four pages, and there will be a list that's got a bunch of videos. It's going to be on this side, I believe. Yeah, right here.

A. Okay.

Q. There's a list of videos that begins with ETH.MESH.PM.000001, Prolift

Professional Education Videos. Do you see that?

A. Yes.

Q. I have counted 33 videos in that list. Do you have any reason to dispute that's about how many there were there?

A. No, I will take your word for it.

Q. When was the last time you watched any of those videos?

A. I don't remember exactly when, but some of these videos I had seen in the past and was familiar with them, but you know, what I did with these videos is, and I couldn't tell you which one is which, but I would take the cursor and move along and just familiarize myself with the videos.

Q. Okay. When's the last time you did that with any of these videos?

A. Probably two weeks ago.

Q. And did you do that with all the videos?

A. If they're listed there, yeah. I don't remember exactly when. Some of them I may have seen a long time ago, but I remember videos.

Q. When you say a long time ago, how long are we talking?

A. Oh, it could have been years ago.
Q. As long as ten years back?
A. It might have been. It might have been five years.
Q. Turn to the last page, please. Actually, it's going to be the second-to-last page. I've counted 30 notations of deposition testimony. Does that look about right?
A. Yes.
Q. Okay. Do those represent -- does each one of those represent an entire deposition transcript?
A. I believe so.
Q. Okay. So there's -- we know there's 30 deposition transcripts that you've read front to back in preparation for drafting your report in this case?
A. I scanned some of these. You know, just kind of like going in looking for words that I, you know, cared about. Did I read them word for word, no, no. There was not enough time to do that.
Q. Yeah, that's kind of what I was thinking?
A. Yeah. It's a lot.

Q. It is a lot. Where did you obtain all the deposition testimony that's listed in your reliance list?

A. From counsel.

Q. From the attorneys representing Ethicon in this case?

A. Yes.

Q. When you received deposition testimony from the attorneys working for Ethicon, did you get entire deposition transcripts, or did you just get excerpts, certain pieces of the testimony?

A. I would have to look. I don't know for sure. I assume they were all complete. I assume they were all complete.

Q. Well --

A. I can't tell you for sure.

Q. -- you just got involved in this case about three months ago.

A. That's right.

Q. Can you remember back about three months to tell us whether or not you received from Ethicon's attorneys full transcripts of these depositions or just excerpts?

A. So when I would get a transcript --

just let me answer it this way -- you know, it's usually like four pages on a page, right? And I wouldn't check the page number. I would just kind of scan. So I'm not paying attention to the actual page number, but I'm just scanning it to see what's important to me. Did I read word for word? No, I couldn't have. But no, it didn't seem -- to me, it did not seem ever that it was, like, okay, cherry picking, this is a good thing for you to read. No, it was the transcript, I believe.

MR. CRAWFORD: Objection. Non-responsive to the cherry picking part.

When you received deposition testimony from the attorneys for Ethicon, was it highlighted.

A. No.

Q. Having reviewed the deposition testimony that's listed on your reliance list, did you then ask for additional testimony from any of these witnesses?

A. I didn't know that there was additional testimony, if there was any.

Q. Did you read any of these deposition excerpts and request -- and say, "Hey,

I need to learn a little bit more about what was said in this deposition. Do you have A, B or C?" Did that ever happen?

A. So I object because you used the word "excerpt," and I don't think that we decided that there were excerpts.

Q. Objection overruled.

A. But, no, I did not request anything else.

MR. ROSENBLATT: He's doing my job for me.

Q. To clarify, this reliance list includes articles, literature, videos and a variety of other documents and materials that relate to issues in this case that you have seen or reviewed over the course of your career --

A. Correct.

Q. -- going years back?

A. Correct.

Q. These are not -- strike that.

This is not a list of materials and documents that you have reviewed in their entirety since becoming involved in this case in March or April of 2016?

MR. ROSENBLATT: Object to form.

A. I agree to an extent in that, as you mentioned, many of these go back many years, and that's what I do, right? I mean, I review literature on a weekly basis. I mean, there are always new studies that come out. But I thought it would be important to list the total, again good or bad, that my opinions that have formed over the course of 25 years should be in here in case I need to reference it. But, you know, did I read every word that's here in the last three months, no.

Q. I'm just -- I'm just trying to clarify. It would be incorrect for a juror or anyone else to look at this long reliance list and assume that you have done a comprehensive review and exam of everything in this list since becoming involved in this case three months ago?

MR. ROSENBLATT: Object to form. Asked and answered.

A. So, right, as I said, my opinions that are in my report are based on 25 years of experience, and many of those articles that have shaped my opinion are listed here in the reliance list.

Q. Okay. What, if any, Ethicon

internal documents did you review in conjunction with generating your general causation report in this case?

MR. ROSENBLATT: Object to form. It's on the reliance list.

A. Right, so it includes -- it can't be exclusive or else I can't -- my mind doesn't think that way, but it includes certainly e-mails. It includes design specifications of failure mode analysis, discussions, you know, animal studies, the IFUs. Those are the types of internal documents that I reviewed.

Q. If there are any internal documents -- strike that.

If there are any Ethicon internal documents you reviewed in conjunction with generating your report, they're contained in this reliance list that's included with Exhibit --

MR. ROSENBLATT: I don't know if you marked it to be honest.

Q. -- No. 1 of your deposition. That (indicating).

Is that correct, Doctor?

A. I did the best I could to make sure that what's listed in the reliance list

represents the documents that I reviewed for my general report. Is that what the question was?

Q. Yeah, pretty much.

Are you aware of any Ethicon internal documents that you reviewed in conjunction with generating your report that are not in your reliance list?

A. Not that I'm aware of.

Q. Are the 30 depositions -- strike that.

Are the 30 or so depositions that are listed at the tail end of your reliance list included in those boxes over there?

A. I'm not sure, and I'll tell you why I'm not sure. Some material was sent to me by e-mail or -- not Dropbox but some other. And so some of -- and there were redundancies. So there are some things that are there, some things that I have, and I kind of went between the two when I reviewed them.

Q. So you don't know?

A. I don't know. Can I just say something?

Q. Yeah.

A. I got kind of tired of lugging

around those boxes between my house and my office, that's the truth. You have no idea.

Q. Oh, I do. I do.

A. Oh, my God.

Q. How many times have you been deposed over the course of your career?

A. I don't keep a list, but it has got to be about 25 to 30 times, I guess.

Q. Any idea of how many of those were depositions involving synthetic mesh litigation?

A. No. At least, at least a handful. At least, you know, five or ten.

Q. Have you ever testified in a trial of a synthetic mesh case?

A. I don't know for sure. I know I once was -- it was sort of like a -- maybe you know what it's called. It was like a video deposition, but it was going to be used at trial, right, and it was actually a plaintiff case involving TVT. I was a plaintiff expert. But I don't think it actually went to trial, so.

Q. Okay. You've never gone to the courthouse and taken the witness stand and testified in front of a judge and jury?

A. Sure I have.

Q. Okay. How many times?
A. Maybe about a dozen.
Q. When was the most recent?
A. Oh, it's got to be -- definitely within the last year. You know, I could get that information for you. In fact, I think I -- we produced something I believe in my report about -- I think about trials that I've testified in in the last four years.
Q. Is it in your CV?
A. No. In the CV? No, it wouldn't be in the CV.
Q. Okay. I saw some stuff in your report about it.
A. Where?
Q. I've seen some things in your report.
A. Yeah, I thought so, too.
Q. It's on page 4.
A. Oh. That's it.
Q. "Within the last four years I have testified as an expert in the cases of Hayes v. Jordan; Vercher, Bryant, Smith v. Milhorat; Banks v. Witkowski; Watts v. Davidson; and Taylor-Ricci v. Coutinho and Staffer;" is that right?

A. Yes.
Q. Are any of those cases involving synthetic mesh?
A. I don't remember. I believe -- I don't remember. I don't remember.
Q. Well, which one of those cases is the one you testified at trial in within the past year?
A. Oh. I'd have to look. I just don't remember.
Q. It's one of these that's listed, though?
A. I believe so. I don't remember.
Q. Do you keep anywhere a log of your experience testifying whether it be in deposition or in trials?
A. No. I know I had to put together a list at one point, and I thought I did a couple years ago with -- when I did some work for Bard. Not for Bard. I was working with Greenberg Traurig in Bard litigation for mesh, and I think I had to put together a list for that, and I thought that's where this came from. I don't keep track per se of my depositions. I'm sure I could find out if you need that information, like

when was the last time I testified. I just don't remember.

Q. Have you ever been retained as an expert witness by Bard?

A. Not by Bard. By Greenberg Traurig, and they represent Bard.

Q. Okay. Have you ever been hired as an expert witness aligned with the defense of Bard?

A. Isn't that what we just said?

Q. You know what I'm asking you.

A. I do, but what I'm saying is, and I think it's important to make the distinction, honestly, is that when -- just like in this case, they asked me -- they didn't say, you know, we're hiring you to defend Ethicon or we're hiring you to defend Bard. They're, like, here's the information. We want your honest opinion. Whether you think something, you know, is going on here that we should know about, you know, whether it's good or bad, what is your honest opinion, and that's what I always do whenever I do any kind of legal work.

MR. CRAWFORD: Objection. Non-responsive, move to strike.

Have you ever been involved in any cases involving Bard?

A. When you say involving Bard, what do you mean.

Q. Like women suing Bard.

A. Well, I guess -- well, so put it this way, I know I've been -- I've been involved in cases where Board products have been used, and I've been retained by attorneys representing physicians, but then, I think it's probably two years ago, I was retained by Greenberg Traurig as part of the MDL, you know, to give my opinion about a number of cases. And, again, similar to this, general report about Bard products and then a number of cases of women who were involved in the MDL against Bard. Does that answer your question?

Q. Yeah, I'm trying to figure out how I can ask it in a way where you can answer it.

A. Okay.

Q. Have you ever been hired by attorneys representing Bard in litigation that involves transvaginal mesh?

A. Yes.

Q. Have you ever been hired by

attorneys representing Boston Scientific Corporation in cases involving transvaginal mesh?

A. No.

Q. Have you ever been hired by attorneys representing American Medical Systems or AMS in cases involving transvaginal mesh?

A. No.

Q. Have you been hired by attorneys representing any other transvaginal mesh manufacturer other than Ethicon and Bard?

A. No.

Q. When you were hired by the attorneys representing Bard, did you generate a general causation report?

A. Yes.

Q. Did you also generate case-specific expert opinions?

A. Yes.

Q. On how many different individual cases?

A. I think it was -- oh, I think it's about 20.

Q. How long ago was that?

A. Maybe a year and a half or two years ago.

Q. Did any of those Bard cases go to trial?

A. Not that I'm aware of. Not that anyone made me aware of.

Q. You teach for Boston Scientific Corporation?

MR. ROSENBLATT: Object to form.

A. I don't teach for them, but they have asked me to be an instructor at courses on various topics, transvaginal mesh, slings, laparoscopic sacrocolpopexy.

Q. Have you taught similar courses for Ethicon?

A. I have.

Q. When was the last time?

A. Going back quite a long time ago. It's probably been, oh, gosh, maybe, you know, seven years, I would guess. Seven or eight years.

Q. Do you know what course it was?

A. There were a number of courses. You know, there was a number of cadaver labs for -- you know, going back to the early 2000s, you know, TVT, TVT-O, Prolift, and I believe early on maybe even involved TVT Secur. I don't

think there were any other products that I taught on, I don't think. Yeah.

Q. Did I hear you say earlier that whenever you were contacted by Butler Snow who represents Ethicon in this litigation you asked Butler Snow to provide you with literature and research materials for you to review in conjunction with generating your report?

A. In addition to research I did myself, yes.

Q. Percentage-wise when we look at your reliance list, what percentage of the materials on that list are things that you came up with yourself as opposed to being provided by Butler Snow?

MR. ROSENBLATT: Object to form. Asked and answered.

A. Yeah. I mean -- by the way, excuse me, it's difficult to answer that just because so many of the things that I had in my possession they sent me duplicates of, including abstracts, papers.

So, you know, maybe, maybe 20 percent of the studies, you know, that I hadn't seen before, but then, you know, obviously, I'd

never seen any of the internal documents. Obviously, I had seen the IFUs, you know, and I had seen videos that I had from years ago. So it's really difficult to say.

Q. Some of the videos that appear on your reliance list were provided to you by Butler Snow?

A. Yes.

Q. A couple of breaks ago you were going to look up the literature that supports your opinion that polypropylene is inert and not chemically reactive. Have you had an opportunity to do that?

MR. ROSENBLATT: If we could take a more extended break --

MR. CRAWFORD: Sure. I'm honestly asking if he had a chance to grab it yet.

MR. ROSENBLATT: I don't think so. We weren't sure how long you were going to go. If you want to take a lunch break, we can try to do it over lunch.

MR. CRAWFORD: No, we're on the tail end of this.

THE WITNESS: We can pull it in a very short period of time.

MR. CRAWFORD: Do you have any questions, Paul?

MR. ROSENBLATT: Yeah, I'll have some. And if you want to give me a little bit of time with the Doctor, we'll try to pull the studies that you asked for.

BY MR. CRAWFORD:

Q. And there was another one, too, right?

A. Yeah, the dyspareunia -- the path reports with the resection of the mesh, right?

Q. Okay.

A. Chronic pain versus voiding dysfunction. Yeah, that's it.

Q. Okay. For the time being I'll pass the witness.

(A break was taken.)

EXAMINATION

BY MR. ROSENBLATT:

Q. Dr. Rosenblatt, my name is Paul Rosenblatt from Butler Snow representing Ethicon and Johnson & Johnson.

You were asked some questions today about Dr. Rosenzweig's report. Do you recall

that?

A. Yes.

Q. And, in fact, that report was Dr. Rosenzweig's TVT report, right?

A. Correct.

Q. And you were asked a significant number of questions about TVT in this deposition?

A. Yes.

Q. And stress urinary incontinence procedures?

A. Yes.

MR. ROSENBLATT: And, Counsel, I think you'll stipulate that this deposition will also satisfy as the TVT general deposition?

MR. CRAWFORD: I don't know that I'm qualified to make any sort of stipulation like that.

MR. ROSENBLATT: Don't sell yourself short like that.

Would it be fair to say, Doctor, that in addition to reviewing -- strike that.

Would it be fair to say, Doctor, that you considered not only Dr. Rosenzweig's report but also the reports from other plaintiffs' experts regarding Ethicon's prolapse

and SUI products.

A. Yes.

Q. And, in fact, you mentioned that you asked for the good and bad. Did you in fact review a significant number of the materials cited in plaintiffs' experts reports?

MR. CRAWFORD: Objection to form.

A. Yes.

Q. And that would include internal documents and medical literature that plaintiffs' experts referred to?

A. Yes.

Q. And did reviewing any of those materials change your opinions about the safety and efficacy of Ethicon's prolapse and incontinence products?

A. I took it into consideration, but it didn't change my opinions.

Q. And in addition to our law firm providing you with some of the materials referenced in your reliance list, would it be fair to say that a significant number of those materials you had already seen previously?

A. Yes.

Q. And, in fact, that's part of your

job as a physician, is to continuously review the medical literature?

A. It's my job as a physician, and it's also my job as an educator. You know, I have residents and medical students and fellows that I teach. I do a lot of teaching around the country and around the world, and I feel it's important to stay up on the literature.

Q. And where do you -- just so we have an understanding -- I know we could run through your CV, but Doctor, where do you teach?

A. Primarily at Mount Auburn Hospital which is a community teaching hospital of Harvard Medical School.

Q. And in addition to teaching residents and fellows at Harvard, are you also teaching continuing medical education across the country?

MR. CRAWFORD: Objection to form.

A. Yes.

Q. And are you -- strike that.

If you could just describe some of your experience teaching professional education for the Ethicon products?

A. So in addition to, you know, CME

courses, and I teach quite a bit of CME courses here and regionally and nationally, and I also present quite a bit at national and international meetings. But specifically with Ethicon products I started doing some teaching probably back in the year, I would imagine, 2000, and I've done a number of -- many cadaver courses educating surgeons on proper use of Ethicon products which started out, you know, with TVT but then TVT-O and Prolift as well.

Q. Did you ever feel like you were being influenced by Ethicon to promote their products?

A. Absolutely not. It has always been very important to me to offer my patients the best treatment. So, you know, I never wanted to be seen that I was working for one company. I use the products on my patients that I think are the best. I've used products from various companies, and as well as just, you know, not always products, right? I mean, you know, techniques and, you know, custom-made pieces of mesh. And if I believe in a product like I believe in, you know, TVT or Prolift, then I would agree to, you know, to instruct surgeons on

the correct use. But there were times I've been asked to, you know, teach for products that I wasn't -- that I didn't believe in, that I didn't use, and I wouldn't teach those products.

Q. And Doctor, were you paid for your time to teach professional education?

A. Yes.

Q. And how did -- the amount that you were paid for your time teaching or strike that.

Doctor, what was the opportunity cost of you teaching professional education as far as --

A. So let's clarify that for a moment. So when I teach a CME course, most often it doesn't involve any payment to me. That's something that I do 'cause I really enjoy teaching, and I think it's a really important thing for some surgeons who are dedicated to do that type of work. But when it involved a specific company like Ethicon, they were often, you know, taking time away from my practice, and so, you know, I think I was compensated fairly for that because that's the opportunity cost. I'm not seeing patients in the office, and I'm not doing surgery on those days. But there's

also teaching in the evenings and teaching on weekends that took me away from my family, but I really enjoyed the teaching, and I think I was compensated, you know, appropriately for that.

Q. So did you teach professional education because you wanted the money?

A. It was not -- it's never been about the money. It's been about teaching proper use of devices. And I've always seen it as not the responsibility of the companies themselves to do the teaching but of the surgeons who are thought leaders in our industry to properly instruct other surgeons on how to use products appropriately.

Q. And I think that's what you referred to earlier as, what, peer-to-peer teaching?

A. Correct.

Q. And, Doctor, in addition to the material -- well, the materials referenced in your report, would it be fair to say that not only have you reviewed a significant number of those materials prior to becoming involved in the litigation but that you in addition to reviewing those materials performed your own PubMed

searches to satisfy yourself of the medical literature?

A. Yes.

Q. And when you were asked questions about the levels of evidence, if you could just explain why Level I and Level II evidence is significant to you?

A. Yeah. So there are many -- there are many reports out in the literature, and they vary in terms of their quality, and it's generally recognized that the highest quality studies are randomized prospective studies or RCTs, randomized controlled trials, and obviously, there are other Level I evidence or ways to kind of synthesize all the data that's put together which is referred to as a meta-analysis. And a meta-analysis is a statistical form where you can pool data from high level studies to try to make sense on a grander scale of the significance. And then also systematic reviews where you have a, you know, a question that you want answered and you look at all the high quality evidence, and it's a matter of, you know, throwing out studies that aren't as useful. You know, there are still studies like

prospective studies or even retrospective cohort studies that provide some use and are considered generally Level II evidence, but they're not as high as the Level I evidence. So we tend to in general in all of medicine, not just in surgery but also in medicine looking at, you know, drugs, et cetera, that Level I evidence is the most important.

Q. And when you look at that Level I evidence, for example, the randomized controlled trials for prolapse meshes involving polypropylene and specifically Ethicon's Gynemesh® PS and Prolift, what is the statistical significance, if any, when those RCTs compare native tissue repairs to mesh repairs for prolapse?

A. Well, there are a couple of ways of looking at it. And when you look at objective success, in other words, based on pelvic examination, across the board the success rate is significantly higher for transvaginal mesh. It's become widely accepted in our field that it's important to look at subjective outcome as well and coming up with like a composite score. And there's good Level I evidence as well that

subjective outcome is either improved or not significantly different from native tissue repair, but in total, you're going to prevent recurrences from happening with transvaginal mesh compared to native tissue repairs.

Q. And when you look at the randomized controlled trials for transvaginal mesh to treat prolapse versus native tissue repairs, is there any statistical significance regarding de novo dyspareunia?

A. You know, that's something we talk about as, you know, mesh and dyspareunia, but when you look at the randomized controlled trials, there is no statistically significant difference in the highest level studies. In fact, there are studies that show less de novo dyspareunia with transvaginal mesh compared to native tissue repair.

Q. And I believe in your expert report you referred to specifically the Withagen study to support that?

A. Correct.

Q. Okay. And would the same be true, Doctor, for pelvic pain and just general quality of life?

A. Those are -- those as well. There's no statistically significant difference between native tissue repairs and transvaginal mesh when you look at those.

Q. And it's important to look at those subjective factors in the context of a randomized controlled trial to make sure you're not comparing apples and oranges but that you're comparing apples to apples; is that fair?

A. That's correct.

Q. Doctor, two of your invoices were marked as I believe Exhibits 4 and 5. Would it be fair to say that you charged for your time in performing the research and rendering your opinions in this litigation?

A. As best I can, yes.

Q. And, in fact, there was a charge of your deposition rate that you submitted on your invoice because -- not because of counsel's fault but your deposition was originally scheduled several weeks ago and was cancelled at the last minute; is that fair?

A. I remember distinctly. The deposition was scheduled for a Monday, and I found out that the deposition was cancelled on a

Saturday. And Monday is -- Mondays and Wednesday are my primary surgical days, and I have block time, and that day would have been filled with, you know, three to six cases, and a week before the block time, the block gets released, and there's no way to -- so that was a wasted day, a completely wasted day.

Q. And, Doctor, we talked a little bit about some of your teaching experience contained on your CV, but would it be fair to say that you've published a significant number of studies in the medical literature on incontinence and prolapse?

A. Right, primarily my field of interest is prolapse, urinary incontinence and fecal incontinence.

Q. And are you involved in any editorial activities such as reviewing for medical journals?

A. Yes, I'm a peer reviewer for a number of journals, and I've been on the editorial board of the Gold journal which is the Journal of Female Pelvic Medicine Reconstructive Surgery and also the JMIG which is more of the minimally invasive gynecologic surgery.

Q. And you mentioned Female Pelvic Medicine Reconstructive Surgery, that would be abbreviated FPMRS?

A. Right.

Q. Is that a subspecialty in your field?

A. Correct.

Q. And that would be a board certification?

A. Correct, it became a board certification I think it was 2013.

Q. And so if Dr. Rosenzweig has not sat for the FPMRS board, then he would not be a board-certified urogynecologist?

A. That's right.

Q. You are, though, right?

A. I am.

Q. And are you in fact an examiner for the FPMRS exam?

A. Yeah, I'm actually a board examiner for the general boards, but I just transitioned to being a board examiner for the subspecialty of FPMRS.

Q. So it would be fair to say, then, Doctor, that you would have a good understanding

of what fellows and surgeons are expected to know in your field about procedures and risks associated with those procedures including pelvic mesh, correct?

MR. CRAWFORD: Objection to form.

A. No, that's correct. That's -- you know, what we do as board examiners is -- I'm very familiar with the standard of care, and we are making sure that people who are quali- -- you know, that the only people who become board certified are qualified to do so and are performing within the standard of care.

Q. And, for example, would you test fellows and surgeons on their knowledge of potential complications of mesh-based repairs for incontinence and prolapse?

A. Yes.

Q. And how to manage those complications that may occur?

A. Correct.

Q. And the same would be true for native tissue repairs for stress urinary incontinence and pelvic organ prolapse?

A. Correct.

Q. Doctor, you were asked some

questions about whether or not mesh exposure was a serious complication. Do you recall that line of questioning?

A. Yes.

Q. In your experience, are mesh exposures typically considered serious complications?

A. So the vast majority of them are not from a clinical standpoint considered serious complications. Could there be a mesh erosion? Let's take away exposures. Could there be a mesh exposure that's serious? Yeah, it could happen. You know, I've seen a couple examples in 15 years of patients who have developed hematomas who have opened their incision and have large mesh exposures but the vast majority, I'm talking about over 95 percent of them, are usually minor mesh exposures that can either be taken care of in the office or can be taken care of in an operating room under local anesthesia with conscious sedation. So how we look at them as clinicians versus how the FDA classifies them because it's a return trip to the OR, there's a disparity there.

Q. And if there is a complication

associated with a native tissue repair, does that get reported to a MAUDE database?

A. No, because it doesn't involve -- as far as I know, it doesn't involve a device, so no one would report it to a MAUDE database.

Q. And so when you were seeing you didn't necessarily agree with the FDA's 2011 public health notice description as complications are not rare, was that in part because they did not consider the complications that occur with native tissue repairs?

A. Correct.

Q. And was that also in part because when you performed the mathematical calculation as you described, 0.6 percent would in fact be rare?

A. In my book, that's very rare.

Q. Doctor, if we look at your expert report, starting on page 33.

A. Yes.

Q. In the middle of the page, you cite to the Damoiseaux 2015 RCT. Do you see that?

A. Yes.

Q. A little further down they describe a mesh exposure rate, but then, even though there

were some mesh exposures with the mesh group, did that translate into any statistical significant difference with respect to dyspareunia or pelvic pain?

MR. CRAWFORD: Objection to form.

A. No, it did not.

Q. And if you look on the next page, 34, you cite to the Heinonen 2016 study.

A. Yes.

Q. And although you describe here that the authors reported a 23 percent mesh exposure rate, you note that the exposures were asymptomatic in 24 of 32 or 66.7 percent of patients. Do you see that?

A. That's correct.

Q. So, if you could, just describe whether or not an asymptomatic mesh exposure would be of any clinical concern?

A. So it depends on the situation but, you know, many women do have small mesh exposures and are not aware of it, and it doesn't pose any danger to the patient, and there's no reason to treatment an asymptomatic mesh exposure. And when I say asymptomatic, I'm talking about for the patient, and if the patient is sexually

active, to her partner. So, obviously, if the patient didn't have symptoms but her partner had symptoms, then that would be symptomatic, but the majority of these mesh exposures are asymptomatic to the patient and her partner.

Q. And, Doctor, I don't want to rehash everything that's already in the report, but would it be fair to say if you continue flipping the pages that you describe a significant number of studies and the reported outcomes to include success rates and complications of those studies involving Prolift and Gynemesh® PS?

A. Yes.

Q. And I do want to look at one in particular on page 37. Towards the bottom you cite to De Landsheere and Cosson in 2011 which was a three-year follow-up study of 524 patients, and then on the next page, could you just describe some of the complications that were noted in this large patient study?

MR. CRAWFORD: Objection to form.

A. So in that study, which I believe was a cohort study -- it was not one of the randomized controlled trials, but it was a very large study because it had, you know, so many

patients in it -- the total mesh-related complications was 3.6 percent with a mesh exposure rate of 2.7 percent which is relatively low. And the other important part about this study was that most of the mesh exposures occurred in the first year of the study, so we're not seeing mesh exposures that are continually coming out. It's usually during the healing process when you see a mesh exposure.

Q. Is that supported by additional studies that you've seen in the medical literature?

A. Yes.

Q. And would that also be supported by your clinical experience?

A. Yes.

Q. Would that also be supported by your discussions with colleagues?

A. Yes.

Q. And what did the De Landsheere study find with respect to severe symptomatic mesh retractions?

A. That it was found in an extremely low number of patients of less than half a percent.

Q. And would that be consistent with what you would expect from Prolift?
A. Yes.
Q. Doctor, you were describing some factors that could contribute to mesh exposures earlier. Do you recall that testimony?
A. Yes.
Q. And I believe you mentioned surgeon technique and other patient factors. So would it be fair to say that there are factors unrelated to the mesh itself that contribute to mesh exposures?
A. Yes, that's widely accepted.
Q. And I believe you also testified that exposure or erosion is not necessarily unique to mesh because you can also have a suture erosion or exposure; is that correct?
A. Correct.
Q. Okay. Would that be true for any foreign body implant?
A. Absolutely.
Q. Do you implant urethral sphincters?
A. I do not.
Q. Do you know if urologists in your field do?

A. Mm-hmm, yes.
Q. Do you know if there's literature to suggest that urethral sphincters can erode?
A. Urethral sphincters, anal sphincters, anything in that area can erode.
Q. And, Doctor, you were asked a number of questions regarding Dr. Rosenzweig's TVT report and whether or not you agreed or disagreed with those opinions. Do you recall that?
MR. CRAWFORD: Objection to form.
A. Yes.
Q. And a lot of those questions dealt with properties of the mesh and potential complications of mesh; is that fair?
A. Yes.
Q. If you could, just -- I know you have a lot of that in your expert report, but if you could just briefly describe your experience with mesh design and mesh properties?
MR. CRAWFORD: Objection to form.
A. Well, I've actually -- I personally have been -- besides reading the literature, which I'm very familiar with, but I've also had the opportunity to work with a number of

companies on mesh designed. And so I've worked with engineers on some of my own products and some with companies and some completely independent.

So, you know, I've approached -- for instance, there's a company in Rhode Island called Biomedical Structures that I, right outside of Providence, that I worked with them on some of my own mesh designs. So I'm very familiar with design of polypropylene mesh.

I've also worked, again, personally, not with a company, with a mesh manufacturer in Ireland called Proxy Medical that actually does make some mesh for some companies in the United States, including Boston Scientific, on devices that I've designed. So I've worked with engineers, design engineers, on mesh design.

MR. CRAWFORD: Objection. Non-responsive.

Q. And would it be fair to say that you also have -- strike that.

Doctor, could you describe your experience, if any, with respect to taking a new product through the regulatory cycle and drafting

IFUs?

MR. CRAWFORD: Objection to form.

A. Yeah, so I've been very fortunate that I've taken -- there was one device that I worked on -- that I've been working on since 2004 which is a mesh device, very similar to the Prolene® mesh. It was actually with American Medical Systems. It was actually very similar to the SPARC mesh that they use, but it was different. It had additional fibers added to it. And that's something I worked with them from 2007 'til this year on designing the mesh, working on the device of the IFUs and other materials, including, you know, animations and online training, et cetera.

So I've taken that product from the beginning through IDE studies, investigational device exemption studies, and the PMA process, premarket approval I think it stands for. So I've been very involved in that type of design. Plus, I wrote much of the instructions for use, the IFUs, for that device.

MR. CRAWFORD: Objection. Non-responsive.

Q. And, Doctor, as part of your

experience teaching professional education, would you teach on the IFUs?

A. Right. So when we teach, what we're doing is sort of summarizing the IFUs, because, you know, the IFUs come with the device, right? So when you open up a package in the operating room, you're really not going to sit there while the patient's under anesthesia and read the instructions like you're programming a VCR. I don't know if people know what a VCR is anymore.

Q. Good lord.

A. Yeah, I shouldn't have said that. I meant a Beta max. Yeah, I got to rethink that.

Anyway, so I think the way most surgeons learn how to use a device is by, or should learn how to use a device, is by going to professional education conferences and learning from PowerPoint presentations, animations, cadaver dissections, procedural videos. That's how people really learn.

Q. By medical literature?

MR. CRAWFORD: Objection. Non-responsive.

A. And medical literature. And that

is basically encompassing what is in an IFU.

Q. And if you had any concerns about Ethicon's IFUs for the TVT products or the Gynemesh® PS or the Prolift devices as being inadequate, would you have voiced your concerns?

A. Yes.

Q. And in your opinion, are those IFUs, all the versions that you've reviewed, adequate?

MR. CRAWFORD: Objection to form.

A. Yes, they are.

Q. And you were asked some questions about your legal work, Doctor. Would it be fair to say that you have been an expert for both sides, both plaintiffs and defendants?

A. Yes, I have. I would say more so for defense, but I have done plaintiff work as well.

Q. Doctor, you were asked about shrinkage and whether or not -- I believe it was couched just in broad terms about mesh shrinkage. Do you recall those questions?

A. Yes.

Q. I believe one of the documents that you cited to was the Dietz paper.

A. Yes.

Q. And what does the Dietz paper regarding TVT describe about whether or not TVT contracts or shrinks?

A. So this is one of the studies that I relied on, and Dr. Dietz is very well for his work on transvaginal ultrasound, and this study shows that the TVT does not seem to contract or shorten over a period of over a year and a half.

MR. CRAWFORD: Objection. Non-responsive.

Q. And in another study by Lo, which was an ultrasound study, what did Lo and colleagues find about whether or not ultrasound assessment found any shrinkage or contraction with TVT?

A. They also -- and, again, both of these researchers are very well-known. Lo is in Taiwan, and showed that TVT does not show any shrinkage. And if -- and there's actual clinical data to support that, in that if shrinkage did occur you'd expect to see patients who were initially voiding. If shrinkage occurred, they'd go into retention, and we just don't see that happening.

MR. CRAWFORD: Objection. Non-responsive.

Q. And do you recall in the 17-year Nelson study whether or not they noticed any shrinkage of TVT?

A. They did not notice any shrinkage of TVT.

Q. And would that be consistent with your medical practice?

A. Yes.

Q. Would that be consistent with your discussions with colleagues?

A. Yes.

Q. And would that be consistent with your general review of the medical literature?

A. Correct.

Q. And additionally, another Dietz paper that I believe you referred to looked at prolapse meshes. I believe in particular the AMS Perigee. Do you recall that paper?

A. Yes.

Q. Is the Perigee similar to the Prolift?

MR. CRAWFORD: Objection to form.

A. It's similar in that it is a Type 1

macroporous monofilament polypropylene mesh.

Q. And what was Dietz's conclusion in this paper from 2011 about whether or not Perigee or transvaginal mesh for prolapse contracted?

A. Yeah, there was no evidence on ultrasound examination of any mesh contraction in this study.

Q. And, Doctor, you were asked some questions about biocompatibility and inertness. I want to show you a paper that I believe you reviewed by Binnebösel. If you could, just describe what they noted about mesh integration.

A. So they stated that these materials are physically and chemically inert, stable and non-toxic.

Q. And they're referring to polypropylene meshes?

A. Yes, they are.

Q. Doctor, you were asked some questions about the Burch procedure. When you were describing your experience with the Burch, were you describing the open Burch or the laparoscopic Burch?

A. Both.

Q. And do you primarily -- do you

still perform open Burchs on a regular basis?

A. No, I use to, but I haven't done an open Burch in probably 20 years.

Q. And why is that?

A. Oh, just because we can do the exact same procedure in a minimally invasive fashion.

Q. So would it be fair to say that the Burch is a -- the open Burch is a more invasive procedure than, for example, a midurethral sling?

A. Significantly more invasive.

Q. And what are some of the -- strike that.

Now, with regard to the Burch, are you familiar with an article by Demirci describing the long-term results of the Burch?

A. Yes.

Q. And what did this paper by Demirci find about the rates of dyspareunia and growing pain as late complications of the Burch?

A. Yeah, so these are potential complications in a Burch procedure, and you know, dyspareunia occurred in 6 patients out of the 220, groin or suprapubic pain in 15, which is probably about, you know, 7 percent or so, but

there were also other complications including enteroceles in over 10 percent of patients and rectoceles, and it's felt that the change in the axis of the vagina predisposes to posterior, which would be rectocele and enteroceles, prolapse.

Q. And would that be a complication that would occur more frequently after a Burch than after a midurethral sling?

MR. CRAWFORD: Objection to form.

A. Yes.

Q. And it would be fair to say, Doctor, that complications such as dyspareunia and pain, whether it's short term or chronic, are well-known complications of any vaginal procedure?

A. That's correct.

Q. You were asked some questions about degradation, and I believe you referred specifically to the Clavé paper.

A. Yes.

Q. What did the authors conclude about their hypotheses concerning degradation, specifically oxidation degradation?

A. They brought up these as

hypotheses, but they stated that none of their hypotheses, and in particular direct oxidation, could be confirmed by the study.

Q. So, Doctor, when you said you were not familiar with the literature that described in vivo degradation, would it be fair to say that scientists have tried to study that issue but have not been able to confirm in vivo degradation?

MR. CRAWFORD: Objection to form.

A. That's correct.

Q. And you were asked some hypotheticals, Doctor. Hypothetically if degradation did occur, what in your opinion, based on your clinical experience and your review of the medical literature, would be the clinical significance of degradation if it hypothetically did occur?

A. So when it came to like slings, you would expect to see failures, and we're not seeing that. And when it comes to prolapse, then you'd expect over time to see degradation would lead to disappearance of the mesh and failures, and that's just not what we're seeing clinically.

Q. And, Doctor, AUGS and SUFU released

a Frequently Asked Questions by Providers regarding midurethral slings for stress urinary incontinence. Have you seen this document before?

A. Yeah, I use that with my patients, too.

Q. And one of the questions that they ask is does the midurethral sling made of polypropylene degrade over time. Could you just summarize what their response was in this document?

MR. CRAWFORD: Objection to form.

A. So AUGS and SUFU are the leading organizations for surgeons and patients in urogynecology and female reconstructive surgery, and it's stated here that polypropylene is a stable and well-accepted biomaterial with, as we mentioned, a history of over five decades in use -- of use in mesh implants. And though people have raised the issue of possible degradation, including what we talked about like cracked surfaces, that there's no evidence that that is actually happening.

Q. And Doctor, one of the other studies that I believe you relied on was a 2011

study by de Tayrac which followed the Clavé study, and you noted earlier this biofilm when you wash it off the mesh wasn't degraded. Could you just describe what the authors found in this study --

MR. CRAWFORD: Objection.

Q. -- in 2011?

MR. CRAWFORD: Objection to form.

A. So what these authors showed is that when you properly washed the material with, in this case, DMSO which is a solvent -- it's actually a byproduct of the wood industry -- and you also used ultrasonic shock, that after the biofilm was removed there is absolutely no polymer degradation, and you know, according to this, scanning electron microscopy image, to my eyes and anyone who would read this, it looks like it's pristine material.

MR. CRAWFORD: Objection. Non-responsive.

Q. And, Doctor, I believe one of the other studies you were relying on was a recent study from the International Urogynecology Journal by Ong. Do you recall that?

A. Yes.

Q. What did this study conclude about explanted Prolene® meshes and whether or not they underwent any clinically significant degradation?

A. Well, they concluded something very similar in that these explanted Prolene® meshes did not undergo any meaningful or harmful degradation in vivo but that the, you know, quote/unquote, cracked layer was actually composed of protein coatings arising from a well-established phenomenon occurring immediately upon implantation which is what we referred to earlier as a biofilm.

Q. And, Doctor, you were asked some questions about the MSDS. I represent to you this is the Sunoco MSDS for Ethicon's Prolene®.

A. Yes.

Q. Would it be fair to say that MSDS, material safety data sheets, are under the purview of OSHA and not the FDA?

MR. CRAWFORD: Objection to form.

A. That is correct.

Q. And so in your opinion would this document have anything to do with the safety of an implantable medical device outside of the context of employees working with various

chemicals?

MR. CRAWFORD: Objection to form.

A. Right, so the MSDS, as you mentioned, is under the purview of OSHA to protect workers who are handling materials, but we're talking about raw materials. We're not talking about devices that are then -- you know, this refers to, for instance, like the polypropylene pellets and when they're heated up and extruded, but that has nothing to do with when it's implanted into a human.

Q. And one of the references I believe Dr. Rosenzweig was citing to under incompatibility was strong oxidizers such as chlorine, peroxides, et cetera, and you were asked questions about whether or not mesh would undergo oxidative degradation due to peroxides in the vagina. Do you recall those questions?

MR. CRAWFORD: Objection to form.

A. Yes.

Q. In your opinion, is that a realistic possibility?

MR. CRAWFORD: Form.

A. No, there's no evidence of that. In addition, you know, again, this is the MSDS

for polypropylene, but then there are additives in Prolene® mesh which are antioxidants.

MR. CRAWFORD: Objection. Non-responsive.

Q. Doctor, if you were going to offer the opinion in a court of law that polypropylene mesh was incompatible in the human body because of an MSDS sheet, in your opinion would that be relying on sound evidence-based medicine?

MR. CRAWFORD: Objection to form.

A. Absolutely not.

Q. Doctor, are you familiar with a paper by Ashley King and Howard Goldman regarding whether or not polypropylene causes cancer or could be cytotoxic?

A. Yes.

Q. What did those authors conclude about whether or not that was a concern of polypropylene midurethral slings?

A. So they concluded that there's absolutely no evidence in the medical literature that polypropylene slings are associated with a risk of malignancy.

Q. And, Doctor, you were asked about chronic inflammatory responses, and I want to

show you a paper I believe you relied on by Firoozi and Goldman at the Cleveland Clinic.

A. Yes.

Q. And this study involves a total of 23 patients involving removal of mesh, prolapse mesh, including Ethicon's Prolift. Do you recall that?

A. I do.

Q. And, if you could, just describe whether or not their removal procedure was successful without removing the arms of the mesh?

MR. CRAWFORD: Objection to form.

Q. In terms of curing the patient's pain?

A. Well, I think one of the most important parts of this study was that they were able to show that patients who had pain where they determined they wanted to remove the mesh that they could remove the mesh safely.

MR. CRAWFORD: Objection. Non-responsive.

Q. And, Doctor, is that consistent with your clinical experience?

A. It is.

Q. And if there's an instance where

you need to leave the mesh in place or it's not easily accessible, do you generally have any concerns, based on your experience and review of the literature and your review of patients, as to leaving mesh in that patient if they don't have any significant complaints?

A. So, first of all, it is extremely rare in my experience and in the medical literature to have to remove mesh totally. And in my experience, patients who do present with pain after prolapse operations such as, you know, armed transobturator mesh systems, if you just relieve the tension on the mesh arm the pain will go away. Mesh itself does not cause pain, but it can cause pain where it inserts into the pelvic floor muscles. And there are techniques that have been described. In fact, one was described by one of my former fellows, and I've shown this in videos, of getting into the space of Retzius laparoscopically and just relieving the tension on the mesh arms and successfully treating women with pelvic pain.

Q. And so would it be fair to say that you're able to successfully treat women who may have some pain after a mesh procedure without

performing significant dissection?

A. Correct.

Q. And in terms of severity of pain, is it an accurate statement that any mesh -- any patient who has mesh undergoes more severe pain or dyspareunia than a patient who had a native tissue repair for prolapse?

MR. CRAWFORD: Objection to form.

A. That is not true.

Q. And is that based on your clinical experience, Doctor?

A. That's based on my clinical experience, but it's also based on the literature, that patients with native tissue repairs can have significant pain. The one that comes to mind is posterior repairs went anywhere from 19 to 32 percent of women with undergoing levator plication can have significant dyspareunia, and there is -- so pain and dyspareunia can happen with any native tissue repair.

Q. So would it be fair to say that pain and dyspareunia are not unique to mesh?

A. That is correct.

Q. And counsel asked you to look

during a break for a study to support your opinion about inflammatory response and whether or not a chronic inflammatory response correlated to chronic pain. Could you just describe that article that you were able to find?

A. Right. So this is an article by Audra, A-U-D-R-A, Jolyn, J-O-L-Y-N, Hill in the International Urogynecology Journal from 2015 where they excised portions of mesh for both voiding dysfunction as well as pain and interestingly found that mesh excised for voiding dysfunction demonstrated elevated levels of inflammation compared to mesh that was excised for pain and/or exposure.

Q. And what else did they conclude or how else did they summarize that?

A. Well, basically in their summary they stated that vaginally placed midurethral slings that are excised for voiding dysfunction demonstrated elevated levels of inflammation compared to mesh that was excised for pain or exposure.

Q. So does this study in addition to your clinical experience and review of other medical literature support your opinion that a

chronic inflammatory response is not indicative or causally related to chronic pain?

A. That is correct.

Q. And, in fact, if you look at another study by two of plaintiffs' experts, Dr. Klosterhalfen and Dr. Uwe Klinge from 2002, what did they conclude in this paper about describing the long-term biocompatibility of surgical mesh?

A. They concluded that long-term incorporation of polypropylene mesh in humans has a more favorable tissue response with increasing implantation interval.

Q. And similar to the Hill article, what did Klosterhalfen and Klinge note about any correlation between an inflammatory response and chronic pain?

MR. CRAWFORD: Objection to form.

A. So they concluded that, and they mentioned it was striking that there was very little difference in inflammatory response in mesh removed for recurrence or for chronic pain.

Q. And, Doctor, counsel asked you a number of questions about what specific internal documents can you recall reviewing off the top of

your head. Do you recall that?

A. Yes.

Q. Would it be fair to say that you showed up here with five banker's boxes worth of documents in addition to a flash drive that we'll provide to counsel?

A. Yes.

Q. And those would be materials that you reviewed in some shape or form?

A. Yes.

Q. And while you may not have been able to read every single word of every document, were you at least able to skim through to determine whether or not there was something that caught your eye --

A. Yes.

Q. -- that you wanted to read more closely?

A. That's correct.

Q. And, again, just -- I think I asked you about this, but I want to make sure. When you asked us to provide with the good and the bad, we did in fact provide you with the documents and literature referenced in the body of plaintiffs' expert reports, correct?

MR. CRAWFORD: Objection to form.

A. That is correct.

Q. Doctor, are all the opinions that you've offered in your expert report and today in your general TVT, Prolene®, Gynemesh® PS and Prolift deposition held to a reasonable degree of medical certainty?

A. Yes, they are.

MR. ROSENBLATT: I have no further questions at this time.

FURTHER EXAMINATION

BY MR. CRAWFORD:

Q. Doctor, you just testified regarding several studies, correct?

A. Yes.

Q. And when you were testifying about those studies, you were reading from those studies, weren't you?

A. Yes, I was.

Q. Okay, I need to see them.

Doctor, I've been handed a stack of studies that you were reading from in your testimony to questions asked by defense counsel just now; is that right?

A. Yes.

(Whereupon, Deposition Exhibit 7, "Influence of implantation Interval on the long-term biocompatibiity of surgical mesh" by Klosterhalfen, et al, was marked for identification.)

BY MR. CRAWFORD:

Q. In your examination by defense counsel, did you read from Exhibit No. 7?

A. I did.

Q. How would you describe that report? What's the name of that report?

A. "Influence of implantation interval on the long-term biocompatibility of surgical mesh."

Q. For purposes of time and economy, if you were talking to one of your colleagues, would you say this is the Klosterhalfen report?

A. Yes --

Q. Okay.

A. -- but you know, you want to make sure because authors often write multiple papers, so you want to make sure you're referencing the right paper.

Q. Okay. This document has highlights

on it, correct?

A. Correct.

Q. Are those the highlights you were reading from in your examination by defense counsel?

A. Yes.

Q. Did you put those highlights on there?

A. I did not.

Q. Who did?

A. The counsel did, but I've read these articles myself.

MR. CRAWFORD: Objection. Non-responsive. Move to strike after "counsel did."

(Whereupon, Deposition Exhibit 8, "Histopathology of excised midurethral sling Mesh" by Hill, et al, was marked for identification.)

BY MR. CRAWFORD:

Q. I'm going to show you what was marked as Exhibit No. 8.

Do you recognize that as one of the studies you were reading from in your examination by defense counsel?

A. Yes.
Q. How would you describe it to one of your colleagues, that article?
A. This is the Hill study about histopathology of excised midurethral sling mesh.
Q. Does that exhibit have highlights on it?
A. Yes, it does.
Q. Did you make those highlights?
A. On this particular copy, no.
Q. Did you read from those highlights during your examination by defense counsel?
A. Yes, I did.
Q. Who put those highlights on that document?
A. Attorney Rosenblatt.
Q. The lawyer for Ethicon?
A. Yes.
MR. ROSENBLATT: And, Counsel, I'll just represent I only had one copy, so I showed him my highlighted copy.
(Whereupon, Deposition Exhibit 9, "Current Controversies Regarding Oncologic Risk Associated with Polypropylene Midurethral Slings" by King, et al,

was marked for identification.)

BY MR. CRAWFORD:

Q. Do you recognize the exhibit marked as -- strike that.

Do you recognize the document marked as Exhibit No. 9?

A. Yes.

Q. Is that a study you were referring to in your examination by defense counsel?

A. Yes.

Q. How would you describe that study to one of your colleagues?

A. This is a study by -- the first author is King, and it's "Current Controversies Regarding Oncologic Risk Associated with Polypropylene Midurethral Slings."

Q. Does that document have highlights on it?

A. Yes, it does.

Q. Did you read from those highlights during your examination by defense counsel?

A. I did.

Q. Who put those highlights on that document?

A. Attorney Rosenblatt.

Q. The attorney for Ethicon?
A. Yes.
(Whereupon, Deposition Exhibit 10, "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants" by Clavé, was marked for identification.)
BY MR. CRAWFORD:
Q. Do you recognize the document marked as Exhibit No. 10?
A. Yes.
Q. How would you describe that document to one of your colleagues?
A. This is the Clavé article about polypropylene as a reinforcement in pelvic surgery is not inert.
Q. Does that document have highlights on it?
A. It does.
Q. Did you read from those highlights during your examination by defense counsel?
A. I did.
Q. And who put those highlights on that document?
A. Attorney Rosenblatt.

Q. Is that the attorney for Ethicon?
A. Yes.
(Whereupon, Deposition Exhibit 11, "Long-Term Results of Burch Colposuspension" by Demirci, was marked for identification.)
BY MR. CRAWFORD:
Q. Do you recognize the document marked as Exhibit No. 10?
A. Yes.
Q. How would you --
MR. ROSENBLATT: Just, Counsel, I think that says 11 there.
MR. CRAWFORD: I'm sorry. Thank you.
Do you recognize the document marked as Exhibit No. 11?
A. Yes.
Q. How would you describe that document to one of your colleagues?
A. The first author is Demirci, D-E-M-I-R-C-I, and it's "Long-Term Results of Burch Colposuspension."
Q. Did you read from that document during your examination by defense counsel?

A. Yes.
Q. Did you read the highlighted portions?
A. I did.
Q. And who put those highlights there?
A. Attorney Rosenblatt.
Q. Is that the attorney representing Ethicon?
A. Yes.
(Whereupon, Deposition Exhibit 12, "Biocompatibility of prosthetic meshes in abdominal surgery" by Binnebösel, was marked for identification.)
BY MR. CRAWFORD:
Q. Do you recognize the document marked as Exhibit No. 12?
A. Yes.
Q. How would you describe that document to one of your colleagues?
A. The first author is Binnebösel, and it's entitled "Biocompatibility of prosthetic meshes in abdominal surgery."
Q. Is that document highlighted?
A. Yes.
Q. Did you read from those highlights

during your examination by defense counsel?

A. I did.

Q. Who put those highlights on that document?

A. Attorney Rosenblatt.

Q. Is that the lawyer representing Ethicon?

A. It still is.

(Whereupon, Deposition Exhibit 13, "Does the tension-free vaginal tape stay where you put it?" by Dietz, was marked for identification.)

BY MR. CRAWFORD:

Q. Do you recognize the document marked as Exhibit No. 13?

A. Yes.

Q. How would you describe that document to one of your colleagues?

A. That's the article by Dr. Dietz on "Does the tension-free vaginal tape stay where you put it?"

Q. Does that document have highlights on it?

A. It does.

Q. Did you read from those highlights

during your examination by defense counsel?

A. I did.

Q. Who put those highlights on that document?

A. Attorney Rosenblatt.

Q. Is that the attorney for Ethicon in this case?

A. Correct.

(Whereupon, Deposition Exhibit 14, "Ultrasound Assessment of Mid-Urethra Tape at Three-Year Follow-Up after Tension-Free Vaginal Tape Procedure" by Lo, et al, was marked for identification.)

BY MR. CRAWFORD:

Q. Do you recognize the document that's been marked as Exhibit No. 14 to your deposition?

A. Yes.

Q. How would you describe that document to one of your colleagues?

A. The first author is Lo, L-O, and it's "Ultrasound Assessment of Mid-Urethra Tape at Three-Year Follow-Up After TVT Procedure."

Q. Does that document have highlights on it?

A. It does.
Q. Did you read from those highlights during your examination by defense counsel?
A. I did.
Q. Who put those highlights on that document?
A. Attorney Rosenblatt.
Q. Is that one of the attorneys representing Ethicon in this case?
A. Yes.
(Whereupon, Deposition Exhibit 15, "Mesh contraction: myth or reality?" by Dietz, et al, was marked for identification.)
BY MR. CRAWFORD:
Q. Do you recognize the document marked as Exhibit No. 15 to your deposition?
A. Yes.
Q. How would you describe that document to one of your colleagues?
A. So that's another article by Dr. Dietz, and it's "Mesh Contraction: myth or reality?"
Q. And does that document have highlights on it?

A. It does.
Q. Did you read from those highlights during your examination by defense counsel?
A. Yes, I did.
Q. Who put those highlights on that document?
A. Attorney Rosenblatt.
Q. Is that the lawyer for Ethicon in this case?
A. It is.
(Whereupon, Deposition Exhibit 16, "Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery" by de Tayrac, et al, was marked for identification.)
BY MR. CRAWFORD:
Q. Do you see the document marked as Exhibit No. 16 to your deposition?
A. Yes.
Q. How would you describe that document to one of your colleagues.
A. This is an article by de Tayrac, D-E T-A-Y-R-A-C, and it's entitled "Basic signs and clinical aspects of mesh infection in pelvic floor reconstructive surgery."

Q. Is that document highlighted?
A. Yes.
Q. Did you read from those highlights during your examination by defense counsel?
A. I did.
Q. Who highlighted that document?
A. Attorney Rosenblatt.
Q. Is that the attorney representing Ethicon in this case?
A. Yes.
(Whereupon, Deposition Exhibit 17, "The Myth: In Vivo Degradation of Polypropylene Meshes" by Ong et al, was marked for identification.)
BY MR. CRAWFORD:
Q. Do you recognize the document marked as Exhibit No. 17 to your deposition?
A. I do.
Q. How would you describe that document to your colleagues?
A. That is an article -- an abstract by Ong, O-N-G, and it's entitled "The Myth: In Vivo Degradation of Polypropylene Meshes."
Q. Is that document highlighted?
A. It is.

Q. Did you read from those highlights during your examination by defense counsel?
A. I did.
Q. Who highlighted that document?
A. Attorney Rosenblatt.
Q. Is that the attorney representing Ethicon in this case?
A. Yes.
(Whereupon, Deposition Exhibit 18, "Purely Transvaginal/Perineal Management of Complications From Commercial Prolapse Kits Using a New Prostheses/Grafts Complication Classification System" by Firooz, et al, was marked for identification.)
BY MR. CRAWFORD:
Q. Do you recognize document number -- excuse me.
Do you recognize the document marked as Exhibit No. 18 to your deposition?
A. Yes.
Q. How would you describe that document to one of your colleagues?
A. This is by first author Firoozi, F-I-R-O-O-Z-I, and it's entitled "Purely Transvaginal/Perineal Management of Complications

From Commercial Prolapse Kits."

Q. Is that document highlighted?

A. It is.

Q. Did you read from those highlights during your examination by defense counsel?

A. I did.

Q. Who highlighted that document?

A. Attorney Rosenblatt.

Q. Is that the attorney for Ethicon in this case?

A. Yes.

(Whereupon, Deposition Exhibit 19, Material Safety Data Sheet for polypropylene, was marked for identification.)

BY MR. CRAWFORD:

Q. Do you recognize the document marked as Exhibit No. 19?

A. Yes.

Q. What is that?

A. This is the MSDS for polypropylene.

(Whereupon, Deposition Exhibit 20, "Frequently Asked Questions by Providers Mid-urethral Slings for Stress Urinary Incontinence, was marked

for identification.)

BY MR. CRAWFORD:

Q. Okay. Do you recognize the document marked as Exhibit No. 20 to your deposition?

A. Yes.

Q. Do you recognize that document?

A. Yes.

Q. All right. How would you describe that document to one of your colleagues?

A. This is the Frequently Asked Questions by Providers regarding midurethral slings that is from AUGS and SUFU, A-U-G-S and S-U-F-U.

Q. Is that document highlighted?

A. Yes.

Q. Did you read from those highlights during your deposition?

A. Yes.

Q. And who highlighted that document?

A. Attorney Rosenblatt.

Q. Is that one of the attorneys representing Ethicon in this case?

A. Yes.

Q. Exhibit Nos. 7 through 20 all

documents that were highlighted by defense counsel handed to you which you read from in your deposition, are these all materials that were provided to you by Butler Snow, the law firm representing Ethicon in this case, when you were first hired --

MR. ROSENBLATT: Object to form.

Q. -- as an expert witness?

A. I can't tell you how many, but many of those are articles that I had already pulled myself.

Q. Are any of Exhibits No. 7 through 20 materials that were provided to you by defense counsel Butler Snow when you were retained or in conjunction with your retainment by them for expert witness testimony in this case?

MR. ROSENBLATT: Objection, asked and answered.

A. I thought I answered that.

Q. One more time.

A. Some of them I've already seen, but those were just handed to me, but I'm familiar with all of those.

Q. So you're telling me that you've seen them before. I'm asking you were they given

to you by Butler Snow in the materials that Butler Snow provided to you shortly after you were hired by them as an expert witness in this case?

MR. ROSENBLATT: Object to form. Mischaracterizes the testimony, asked and answered.

A. What I'm trying to say is that, and I can go through each one of them, but many of them I was already familiar with before they were provided to me by Butler Snow.

Q. I understand, but were they all provided to you by Butler Snow regardless of whether you were familiar with them?

MR. ROSENBLATT: Object to form. You mean in addition to him having them himself?

MR. CRAWFORD: Yes, sir.

A. In addition to me having them myself, they were also given to me by Butler Snow.

Q. The copies that were sent to you by Butler Snow, were they highlighted?

A. No. No documents from Butler Snow were highlighted before they got to me.

Q. Are all of these documents marked

Exhibits 7 through 20 included in your reliance list?

A. I would have to check, and the reason I say that is -- can I take a look for a minute?

Q. Sure.

A. The one in particular that I believe is not -- that I know is not in my reliance list, at least I don't think so, is the abstract from the IUGA meeting which has taken place yet. So it was provided recently because the abstracts were recently, you know, published in the International Urogynecology Journal.

Q. One of these articles that's contained in Exhibits No. 7 through 20 was an article I'd asked you for during my examination of you, and you said that you'd check on one of the breaks and you'd get it for me and bring it to me, correct?

A. Correct.

Q. We came back from break and you provided it, correct?

A. Yes.

Q. Did you find it yourself or did defense counsel find it for you?

A. Defense counsel found it 'cause I couldn't find it in my own, but I know it's there. It's in one of these banker's boxes.

Q. And then he highlighted it for you, right?

A. Yes, I think to save time.

MR. ROSENBLATT: Object to form. That was the only copy. For efficiency sake, I printed one copy.

Q. You testified that you reviewed and considered materials that are cited in Dr. Rosenzweig's report, correct?

A. Yes.

Q. Do you know which ones?

MR. ROSENBLATT: Object to form.

A. No, it's been quite a while. I'd have to go back and look at it.

Q. If you look at it, can you tell us?

A. Is this it?

Q. That's a good question. This one is it.

A. Okay. Thank you. Ask me what the question was again.

Q. Well, you've indicated that you've reviewed materials that were attached to

Dr. Rosenzweig's report, and I want to know which of those materials that are attached to Dr. Rosenzweig's report have you reviewed?

A. Not exclusively, but I'm just telling you which ones I recognize that I've reviewed. Clavé, which we talked about, that polypropylene as a reinforcement in pelvic surgery is not inert. I believe that the Coda, C-O-D-A, article. I believe that's in my reliance report. There are others as well. I would have to do the cross-reference to see if they are in my reliance report, but I'm aware of these articles.

Q. Well, I know that -- is there a difference between being aware of the articles and reviewing the articles?

A. No, I have. I have reviewed. I can't say that I reviewed 100 percent of these, but ones I thought were important I looked at.

I know I've seen articles by K-L-I-N-G-E, Kling or Klingy. I don't know which one of these I've looked at, but I have seen those articles.

Q. I know it's late. I know we've been on for a long time.

A. No, I'm okay. Thank you.

Q. And I promise I'm not picking on you. And I'll be completely candid with you, I expect to hear something to the tune of Dr. Rosenzweig not only reviewed all the materials in his report but he also, in criticizing Dr. Rosenzweig, has reviewed all of the stuff Dr. Rosenzweig has reviewed. And if that's not true, I need to know, and that's why I need to know what you've -- what is attached to Dr. Rosenzweig's report that you've reviewed.

A. So I think, in my mind, the important thing is I've reviewed Dr. Rosenzweig's report. He references those other reports. Have I read every one of those other reports, absolutely not, but I know what's contained. What he's doing is summarizing what's in those reports in his report. And I would not expect him to fabricate anything, so I take it at face value his opinions are based on those reports.

Q. That will do. We'll move on. Thank you.

Ethicon approached you to teach students or other doctors about Ethicon products, correct?

A. Correct.
Q. You have also been approached by other medical device manufacturers and asked to teach about their products, correct?
A. I have been, yes.
Q. And there's other products that are manufactured by other manufacturers that you either didn't believe in or weren't compelled to teach because either you don't use them or you just aren't that crazy about the product; is that fair to say?
A. Well, if I'm not crazy about a product, I won't use it.
Q. And you won't teach it?
A. And I won't teach it.
Q. What manufacturers have approached you about -- asking you to teach about their products that you've declined?
A. Caldera, for instance.
Q. What device?
A. Their slings.
Q. Okay.
A. Mentor approached me years ago about ObTape which I was not pleased with.
Q. And who was that? I'm sorry.

A. Mentor, M-E-N-T-O-R. I've been asked about teaching for AMS when they had Elevate, and I declined. Those are the ones that come to mind.

Q. Why did you decline Caldera's offer to teach others how to use their slings?

A. Only in that I wasn't using their slings, and there was nothing particularly wrong with their sling, but I wasn't using it.

Q. Why did you decline Mentor's request to teach others how to use their tape?

A. I did not like the characteristics, the physical characteristics, of their tape.

Q. What about it did you not like?

A. It was a multifilament microporous tape that didn't have the characteristics of a Type 1 polypropylene monofilament that we talked about earlier.

Q. Did the microporous nature of the tape turn you off for lack of a better term?

A. Yes.

Q. Why?

A. Because of the risk of infection and lack of incorporation into the tissues.

Q. Anything else about the Mentor tape

that you didn't like?

A. There were already reports of exposures and erosions, and I didn't feel like it was something that I wanted to get involved in.

Q. Why did you decline AMS's request to teach others how to use their Elevate® product?

A. No other reason than that I was using a comparable product from Boston Scientific at that point and was very pleased with the way it worked on, and I just wasn't -- I had tried the Elevate® product a couple times, and I thought it was fine, but I just wasn't using it, and I didn't think it was right to teach something I wasn't using.

Q. Regarding teaching other doctors how to use Ethicon products, you testified that while you were doing it for the love of teaching -- strike it.

Regarding teaching other doctors how to use Ethicon products, you've testified that you were doing that for the love of teaching, not for the money, true?

A. I could make just as much from my practice by staying, you know, at home and seeing

patients and doing surgery, that's correct.

Q. You testified that you were doing it for the love of the product, not the money. Is that true?

MR. ROSENBLATT: Object to form. Asked and answered.

A. Right. I think I actually said for the love of teaching and teaching products that I was using.

Q. Nevertheless, Ethicon paid you?

A. They compensated me.

Q. How much were you compensated by Ethicon for teaching others how to use their products?

A. I don't remember, but it was in line with what everyone else was getting. As far as I knew, it was fair market value for teaching.

Q. What was everybody else getting?

A. You know, I don't remember 'cause it was over a span of many years, but there were consulting agreements that spelled out what I was making.

Q. How many different consulting agreements have you entered into with Ethicon concerning teaching their products?

A. I don't know.
Q. More than five?
A. Well, I think it -- I think it had a term on it of maybe a year or maybe two years, and so when that was up, I was sent a new consulting agreement.
Q. And for how many years?
A. I'm going to guess it started around the year 2000, and I do not remember the last year that I signed a consulting agreement, but it's got to be at least five years ago.
Q. Five years ago from today would be 2011, correct?
A. Yeah, but that's a rough estimate. I really don't know.
Q. I totally understand we're dealing with a rough estimate --
A. Yeah.
Q. -- but if you started around 2000 and ended in 2011, you were under consulting agreements with Ethicon for approximately 11 years.
A. I think that's about right.
Q. And I'll rephrase the question.
For approximately 11 years from

about year 2000 to around 2011 you were under consulting agreements with Ethicon concerning teaching others how to use their products?

A. Correct.

Q. But as you sit here today under oath as an expert witness in this case involving Ethicon, you cannot recall the compensation rate for any of the consulting agreements you entered into with Ethicon between the year 2000 and 2011?

MR. CRAWFORD: Object to form. Asked and answered.

A. So I would be guessing which I don't want to do but if -- and I'd be happy if -- if my counsel wants me to guess, I'd be happy to guess.

MR. ROSENBLATT: I'd prefer if you did not guess.

Q. I'd prefer for you to estimate, kind of like you estimated that your last consulting agreement with Ethicon was about five years ago. Estimate for me about how much were the consulting agreements?

MR. CRAWFORD: Object to form. Asked and answered, asking the witness to speculate. If you can provide a reliable

estimate, you can do so.

A. My best guess would be that a day of consulting was probably $2,000 dollars to $2,500.

Q. Did that remain the same from 2000 to 2011?

A. I don't remember.

Q. How many days a month were you consulting for Ethicon?

MR. ROSENBLATT: Object to form.

A. I really do not remember.

Q. Do you have an estimate?

A. It was -- I don't even think it was number of days per month. It was probably number of days per year. You know, maybe there were six courses, maybe there were ten.

Q. How many days would a course last?

A. I think it varied, but it was never more than two. It was usually one.

Q. One to two days each course?

A. Correct.

Q. Again, we're using estimates here.

A. Yeah.

Q. And to summarize, you were involved in consulting agreements with Ethicon for

approximately 11 years from 2000 to 2011, correct?

A. Correct.

Q. You're estimating you were compensated approximately $2,000 per day for each day of consulting, correct?

A. I think I said between 2,000 and 2,500.

Q. You would teach approximately six to ten courses per year --

MR. ROSENBLATT: I object to form.

Q. -- is that right?

MR. ROSENBLATT: Assumes facts not in evidence.

A. Yeah, I wish I could be more precise. It may have been less, and it may have been more, and it varied per year.

Q. That's why you're estimating a range which is approximately six to ten courses per year; is that right?

A. Yeah, the best I can recall, yes.

Q. Each course would last between one to two days but no more than two days?

A. Correct.

Q. Did you keep any of those

consulting agreements?

A. I believe -- I probably have kept the last one. I may have others.

Q. If you were going to retain an Ethicon consulting agreement, where would you keep it?

MR. ROSENBLATT: Object to form. Counsel, I think those would have all been produced in the general Ethicon production.

Q. Would they be at your office?

A. They'd either be in my office or in my home.

Q. How much do you charge per day to testify for Ethicon?

A. I think it's listed in my report. So it's $9,000 a day and a day is considered any more than three hours which includes traveling time.

Q. Your deposition was scheduled to start today at 9 a.m., correct?

A. Correct.

Q. And we got started at about that time, right?

A. (Witness nods.)

Q. Right?

A. Correct.
Q. And it's 3 o'clock now, correct?
A. Correct.
Q. So you're in excess of the three hour minimum, right?
A. Correct.
Q. So we're in the $9,000 range today, correct?
A. Correct.
Q. You expect to be compensated $9,000 for your testimony at this deposition today --
A. Correct.
Q. -- which is taking place at the Courtyard by Marriott located at 777 Memorial Drive in Cambridge, Massachusetts?
A. Correct.
Q. Did you also charge for review of materials in preparation for this deposition?
A. I haven't yet but yes.
Q. How long did you spend reviewing materials for this deposition that you'll charge for?
MR. ROSENBLATT: I was just going to say to the best of your recollection.
A. Yeah, I don't have it in front of

me, but if I had to guess, my best estimate would probably be in the, you know, 20-hour range.

Q. How much do you charge for reviewing documents in preparation for this deposition?

A. $800 an hour.

Q. Did you charge for your meeting with defense counsel prior to walking into the deposition this morning?

A. You mean this morning?

Q. Yes, sir.

A. No, that's part of the $9,000 per day.

Q. Did you come from out of town today?

A. I live about 20 minutes from here.

Q. See, I couldn't remember. So that's a no. You didn't stay at the Courtyard last night, did you?

A. It's a different town. It's out of town.

Q. Is it far enough to get a per diem payment?

A. No.

Q. So if you've got $9,000 for your

deposition time today plus $800 per year for 20 hours of depo prep time, that would be $16,000.

$800 per hour for 20 hours is $16,000 charged for your records review in preparation for this deposition.

A. Correct.

Q. Plus there's $9,000 for the actual deposition time, correct?

A. Correct.

Q. So that's a $25,000 charge for the work you've done in preparation for this deposition today?

A. Correct.

Q. This deposition lasted approximately six hours?

A. If you do the math, I believe you.

Q. Well, we're not quite done, but let's say from -- if we started at 9 a.m. and we end right now at approximately 3 p.m., that would be approximately six hours, correct?

A. Yes.

Q. Your report that's been marked as an exhibit to your deposition today, that's your general causation report, correct?

A. Yes.

Q. When you submitted that report to Butler Snow, it was in a different font than what it's in right now; is that right?

A. Yeah, when I say different font, I think it might have been just -- again, I think it was the line spacing. That's why I just wanted to make sure it was mine that you were handing me.

Q. Do you know who modified that report between the time you submitted it to Butler Snow and today?

A. When you say "modified," it was just a change in the format. There's no changes in the language or the words. And do I know who did that --

Q. Yes, sir.

A. -- no, I don't.

MR. ROSENBLATT: Counsel, I'll represent that I double spaced his report, and I put the cover page on there with the case heading because I don't think Dr. Rosenblatt really knew how to format that first page.

MR. CRAWFORD: Thank you, Paul.

One of the exhibits to your deposition is a document related to AUGS; is that

correct.

A. The one that we just read a little while ago?

Q. Yes, sir.

A. Yes.

Q. In fact, it's Exhibit No. 20 to your deposition, correct?

A. Yes.

Q. What is AUGS?

A. AUGS is the American Urogynecologic Society.

Q. In 2013, AUGS released a position statement on surgical options for pelvic floor disorders; is that right?

A. Yes.

Q. Can you summarize what AUGS said in 2013 as it relates to surgical options for pelvic floor disorders?

A. I mean, there have been several position statements that AUGS has released, and I think the one you're referring to is -- well, there are several. There was one that had to do with midurethral slings for stress incontinence, and the other one that I recall is the one that had to do with limiting, you know, limiting

options for pelvic floor reconstruction.

Q. What is your understanding as far as AUGS position on transvaginal mesh used for midurethral slings?

A. Right. So what the position statement was saying for that was that, you know, slings have become the gold standard, that they've been used in millions of women with great success and that it was not the intention of the FDA to limit the use of suburethral slings and that it was a very important procedure for stress incontinence.

Q. Is it fair to say that AUGS advocates the use of transvaginal mesh for --

MR. ROSENBLATT: Object to form.

Q. -- stress urinary incontinence repairs?

MR. ROSENBLATT: Object to form.

A. Yeah, I'm not sure I'd use the word advocates. I don't mean to be splitting hairs, but it is a very important device that the overwhelming majority of AUGS members which represent the primary surgeons in the country from a, you know, urogynecologic standpoint who take care of women who have stress incontinence,

and it's used by over I think it's 95 percent of AUGS members, and that there should be no limiting of that by any, you know, government body.

Q. What's required to gain membership in that organization?

A. Presently paying dues.

Q. How much are the dues?

A. I really don't remember. It's a couple hundred dollars a year.

Q. Is there a board of directors for AUGS?

A. There is.

Q. What does it take to get on the board of directors?

A. It just quoted you. How does that happen?

Q. I don't know.

MR. ROSENBLATT: We'll get Siri to testify.

A. I'm sorry, what were you saying?

Q. How do you get on the board of directors for AUGS?

MR. ROSENBLATT: Object to form.

A. It is usually an elected position.

Q. Who elects you? Who elects the board members?

A. I think names are brought up that are nominated, and then the society itself will vote on the board members.

Q. You've been on the board of directors for AUGS?

A. Yes.

Q. What years did you serve on the AUGS board of directors?

A. Do you have my CV? I believe it was -- 2012 to 2014, I believe. In that time frame.

Q. So you were on the AUGS board of directors when the 2013 position statement was issued, correct?

A. I was, but I was not part of that. I completely support it, but I was not part of drafting that. I think it was drafted right before I came on to the board.

Q. Did you have any involvement in the editorial process concerning that position statement in 2013?

A. No.

Q. Did you vote on it, whether it

should be issued by AUGS?

A. No, I think it was right before I came on the board, I believe. I did not vote on that, but I would have voted for it.

Q. Do you agree with the notion that when trying to determine the credibility of a statement one should consider the relationship between the one making the statement and the one benefitting from the statement?

MR. ROSENBLATT: Object to form.

A. Can you say that again?

Q. Yes. Do you agree with the notion when trying to determine the credibility of a statement one should consider the relationship between the one making the statement and the one benefitting from the statement?

MR. ROSENBLATT: Object to form.

A. Yeah, I think it's kind of a vague statement, but if you gave me a more specific example or maybe how it relates to what we're talking about, I'd be happy to answer that.

Q. Do you agree that whether or not AUGS board members are receiving direct financial benefits from mesh manufacturers is a factor to consider when trying to determine the credibility

of an AUGS position statement?

MR. ROSENBLATT: Object to form. Lack of foundation.

A. I'll just say that I know the members of the board. I know the members of the board when this position statement came out, and I completely believe in their integrity and their motivation, and their motivation and their only motivation is to protect their patients, and I do not believe that there was any influence and financial compensation when they came out with the position statement.

MR. CRAWFORD: I'll object as non-responsive and move to strike.

My question is a little bit more narrow and tailored. I'll ask it again.

Do you agree that whether or not AUGS board members are receiving direct financial benefits from a mesh manufacturer is a factor to consider in determining the credibility of an AUGS position statement about the use of mesh?

MR. ROSENBLATT: Object to form, asked and answered.

A. So I'm going to say it again, that -- by the way, there are some board members,

including the president, the -- I assume it's called the vice president or the president elect. No. Whoever the next in line is. There are several of the executive board who are not permitted to have any potential conflicts of interest.

There are others on the board, myself included at the time, but not during the position statement but while I was on the board, that were permitted to have potential conflicts of interest, but we had to declare those potential conflicts of interest. So as long as you declare those potential conflicts of interest and you have integrity as a person and a physician, then I have no problem with what the position statement would say.

MR. CRAWFORD: I object as non-responsive and move to strike.

Can you answer the question I just asked you with a yes-or-no answer or is that impossible?

A. I think it's impossible.

Q. Okay. Have you ever been involved in a program whereby you were paid by a synthetic mesh manufacturer to mentor other doctors or

promote synthetic mesh products?

MR. ROSENBLATT: I object to the characterization.

A. I've taught at professional education courses, you know, under the support of medical device manufacturers.

Q. Have you ever been part of Boston Scientific's Healthcare Professional or also known as HCP program?

A. If that's what it's called. I guess maybe I am not familiar with that term, but I have taught for Boston Scientific, yes.

Q. As you sit here today, you don't know whether or not you've ever been involved in the Boston Scientific Corporation Healthcare Professional Program?

A. I don't think I've ever heard it referred to as that, but if that's what I've been a part of, then I think the answer is yes. I don't deny it. I just don't know what it's called.

Q. In 2009, did you receive a quarterly payment of $10,000 each quarter from a synthetic mesh manufacturer for participation in a program where you would mentor other doctors or

promote synthetic mesh products?

MR. ROSENBLATT: Object to the form, the characterization of promote.

A. Right, but I'm also asking you are you suggesting that I was paid $10,000 regardless of what I taught?

Q. No, I have no idea what you were teaching. I'm just exploring this issue.

A. Understood. So I don't recall that particular year, but any time I've done any teaching for any mesh manufacturer I've been paid for my services. I have never been paid like a -- what's the word I'm looking for. Like a retainer. I've never been paid as a retainer. I've been paid for my services.

Q. Have you ever received set quarterly payments?

A. No, never.

Q. Is it true that during the years 2011 and 2012, that being the years leading up to the release of the 2013 AUGS position statement, you were paid approximately $100,000 by Boston Scientific Corporation for participation in their Healthcare Professionals Program?

A. I don't have the exact figures, but

that is possible, but I think -- did you say leading up to the position statement?

Q. I said in 2011, 2012. I'll ask it again.

A. Yeah, please.

Q. Is it true that during the years 2011 and 2012 you were paid approximately $100,000 by Boston Scientific Corporation for participation in their Healthcare Professionals Program?

A. If that's what it's called. I did consulting work for Boston Scientific, and it's quite possible that that was the amount of money that I was paid.

Q. You're just not sure if it was called the Healthcare Professionals Program?

MR. ROSENBLATT: Object to form.

A. Correct.

Q. Of the 13 board members who were on the AUGS board when the 2013 position statement was released, how many of them had received financial compensation from synthetic mesh manufacturers during the two years preceding the release of the statement?

A. I have no idea.

Q. Being a former AUGS board member, is that information you would expect to be kept in the regular course of business activity within the AUGS organization?

A. So I guess I missed that point. Being an AUGS member, what was the question?

Q. Being a former AUGS board member, do you believe that the information I just asked you about is information that would be kept in the regular course of business activity within the AUGS organization?

A. Yes.

MR. ROSENBLATT: Object to form.

A. But let me just state that again there is I believe it's called the executive board that are not permitted to have any potential conflicts of interest, but any conflicts of interest, potential conflicts of interest of the other board members is declared and is publicly available.

Q. How is it declared and where is it made publicly available?

A. I don't know. All I know is that at every board meeting we were required to list any potential conflicts of interest, and if we

had a potential conflict of interest that would affect any decisions, we were asked to abstain from those decisions.

Q. Doctor, I appreciate your patience with me in coming out here to talk to us today. At this point in time I don't have any further questions for you. I pass the witness.

MR. ROSENBLATT: I'll be very, very brief.

FURTHER EXAMINATION

BY MR. ROSENBLATT:

Q. Doctor, we were just talking about AUGS position statement. I want to hand you -- what are we on?

MR. CRAWFORD: 21, I think.

(Whereupon, Deposition Exhibit 21, AUGS position statement, was marked for identification.)

BY MR. ROSENBLATT:

Q. I'm going to hand you what's been marked as Exhibit 21. If you could take a second and flip through that.

A. Mm-hmm.

Q. Now, Doctor, do you see any

highlighting on this document?

A. No, I do not.

Q. Good. I will represent to you this is my only copy, but to spare counsel another set of questioning, I will not highlight anything.

Was this position statement initially published in January of 2014 and then updated in June of 2016?

MR. CRAWFORD: Objection to form.

A. It was.

Q. And was this position statement limited to the support of AUGS?

A. No.

Q. And if you could just describe the organizations that joined in showing their support for the AUGS/SUFU position statement?

A. Right. And just so I know is this the one from 2000 -- this is the one from 2016?

Q. Correct.

A. Yeah. So there were other organizations that supported this, including the AAGL, the American Association of Gynecologic Laparoscopists, the American College of Obstetrics and Gynecologists, the National Association for Continence, and the Society of

Gynecologic Surgeons, as well as the Women's Health Foundation.

Q. So, Doctor, it would be fair to say that the support for the AUGS/SUFU position statement on midurethral slings is not limited to professional societies but also patient support groups such as the NAFC and the WHF?

MR. CRAWFORD: Objection to form.

A. That is correct.

Q. And, Doctor, is this position statement something that you would have received on your own? Strike that.

Doctor, is this position statement something that you were made aware of directly through AUGS?

A. Yes.

Q. Is this also something that was provided to you by Butler Snow?

A. Yes.

Q. And so although it was provided to you from Butler Snow, that was not in fact the first time you had seen that document?

A. That is correct.

Q. And the same would be true for a significant amount of medical literature that

we've discussed?

A. That is correct.

Q. And counsel asked you about some of the studies that we looked at earlier where we quickly went through and there was some highlighting on those studies. Do you remember those?

A. Yes.

Q. Had you reviewed those studies prior to today's deposition?

A. Yes.

Q. And when counsel suggested that you were just reading the highlights, would it be fair to say that -- well, strike that.

Would it be fair to say that counsel asked you to provide some of the documents and literature that you had discussed with him earlier today?

A. Can you ask that again?

Q. Would it be fair to say that you provided literature in response to some of the questions that counsel asked today?

A. Yes.

Q. And you in fact asked me to print out some of those studies so that we could move

things along today since counsel asked you to find those during a break; is that correct?

MR. CRAWFORD: Objection to form.

A. That is correct. I mean, we have, you know, one, two, three, four, I believe it's five, yeah, banker's boxes of documents, and just to expedite things, I asked you to print these out. But these are articles that are in here that I've highlighted either here or on my computer.

Q. And counsel asked you questions about your experience teaching for various manufacturers. Do you recall those questions?

A. Yes.

Q. And in his questions, he used the word promote their products. What is your interpretation of whether or not you were or strike that.

What is your understanding of whether or not you were promoting products for these manufacturers?

MR. CRAWFORD: Objection, form.

A. Yeah, so that's never been my goal, is to promote a product for a company. My goal is to share my experience with others. And you

know, just to give you an example, when TVT came out, you know, and I was first very skeptical of it, and then when I started using it, I realized what an incredible advantage it was compared to what I had been using previously. The same was true with TVT-O when that came out. But, you know, just to give another example with the same company, I think it was 2006 is when Ethicon introduced TVT Secur which is a single incision sling, and I wasn't so sure about it. The data was not as compelling as it had been for the other slings, and my center did a randomized prospective trial comparing TVT-O, which is something that we had been using for several years and very happy with, with TVT Secur. This was a study that was funded by Ethicon, and we decided even before we started the study that we would do an interim analysis, and based on the interim analysis, we felt compelled to stop the study because the results were so significantly different between TVT-O and TVT Secur where we were not satisfied with the results, and we published those results.

MR. CRAWFORD: Objection. Non-responsive.

Q. Did Ethicon try to prohibit you from publishing the results of that study in any way?

A. No, never.

Q. Did Ethicon try to retract the funding from that statement because of the data that you presented?

A. No, that was never ever even a question, and it was based on I believe our study and several other studies that were similar studies that Ethicon decided not to -- decided not to sell that product anymore.

Q. And would that be an example of how a product with less mesh such as TVT Secur is not necessarily a better product than something that uses -- than a product that has more mesh such as TVT-O just based on the amount of mesh that's used?

MR. CRAWFORD: Objection to form.

A. That is correct.

Q. And you were asked some questions about consulting agreements with Ethicon. Do you recall those questions?

A. Yes.

Q. The consulting agreements to my

understanding would list a maximum amount; is that consistent with your understanding?

MR. CRAWFORD: Objection to form.

A. Yeah, I do remember that.

Q. So would it be fair to say that the amount listed on the consulting agreement is not necessarily an accurate portrayal of what you were actually paid for any given year?

A. That is correct.

Q. You were asked some questions about how much you're being paid here today and how much you've been paid over the time you were teaching Ethicon professional education.

Do you think that payments you've received from industry for teaching on the safe and efficacious use of products has in any way inhibited your ability to provide a fair and balanced review of the medical literature regarding the products at issue?

MR. CRAWFORD: Objection to form.

A. So, you know, since I started in practice 21 years ago, I've always been committed. My primary interest is helping women and teaching surgeons. I mean, that's what I've been dedicated to being at Harvard, having

medical students, residents and fellows. We started the fellowship in 1999. This is what I'm dedicated to in my career. I would only teach products that I felt that were worthy of being taught and that were excellent products, but my teaching is based on the medical literature, it's based on evidence-based medicine, and I'm very comfortable with that.

Q. And so the fact that Dr. Rosenzweig has testified that he has been paid by plaintiffs' counsel more than a million dollars in the pelvic mesh litigation, that alone would not in itself in your opinion automatically discount his opinions solely based on the millions of dollars he's been paid by plaintiffs' counsel --

MR. CRAWFORD: Objection to form.

Q. -- is that fair?

A. I think it's a fair statement.

Q. All right. Would you agree or disagree that there is a difference between actual bias and a potential for a conflict of interest?

A. Yes.

Q. You would agree?

A. I would agree.

Q. I appreciate your time, Doctor. No further questions.

MR. CRAWFORD: I have nothing further. Thank you very much.

(Deposition concluded at 3:37 p.m.)

C E R T I F I C A T E

I, Maryellen Coughlin, RPR/CRR and notary public in the Commonwealth of Massachusetts, do hereby certify that the foregoing is a true and accurate transcript of my stenographic notes of the deposition of PETER L. ROSENBLATT, M.D., who appeared before me, satisfactorily identified himself, and was by me duly sworn, taken at the place and on the date hereinbefore set forth.

I further certify that I am neither attorney nor counsel for, nor related to or employed by any of the parties to the action in which this deposition was taken, and further that I am not a relative or employee of any attorney or counsel employed in this case, nor am I financially interested in this action.

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING REPORTER.

MARYELLEN COUGHLIN, RPR/CRR

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After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney with thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

PETER L. ROSENBLATT, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public

LAWYER'S NOTES

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